EXHIBIT A

BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND VENTILATOR LITIGATION	MDL Docket No. 3014

NOTICE OF POTENTIAL TAG-ALONG ACTION

In accordance with Rule 7.1(a) of the Rules of Procedure of the U.S. Judicial Panel on Multidistrict Litigation ("JPML"), Defendants Philips North America LLC, Philips RS North America LLC and Philips Holding USA, Inc., write to notify you of the potential "tag-along" action listed on the attached Schedule of Actions

The docket sheet and complaint are attached hereto.

Dated: August 31, 2023

Respectfully Submitted,

/s/ *John P. Lavelle, Jr.*
John P. Lavelle, Jr.
john.lavelle@morganlewis.com
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
Tel: 215.963.5000

Counsel for Defendant Philips RS North America LLC

/s/ Michael H. Steinberg
Michael H. Steinberg
SULLIVAN & CROMWELL LLP
1888 Century Park East
Los Angeles, CA 90067
Tel. 310.712.6670
steinbergm@sullcrom.com

Counsel for Defendants Philips North America LLC and Philips Holding USA, Inc.

BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND VENTILATOR LITIGATION	MDL Docket No. 3014

SCHEDULE OF POTENTIAL TAG-ALONG ACTION

	Plaintiff(s)	Defendants	District	Civil Action No.	Judge
1.	Sharon Lis and Allen Lis	Koninklijke Philips N.V.	W.D. New York	1:23-cv-00907	Unassigned

BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND VENTILATOR LITIGATION	MDL Docket No. 3014

PROOF OF SERVICE

In compliance with Rule 4.1(a) of the Rules of Procedure for the United States Judicial Panel on Multidistrict Litigation ("JPML"), I hereby certify that on August 31, 2023, a true and correct copy of the foregoing Notice of Potential Tag-Along Action was served on all parties electronically via the JPML's CM/ECF system. I further certify that I caused the foregoing to be mailed via the U.S. Mail or e-mail to the recipients identified on the attached Service List.

Dated: August 31, 2023

Respectfully Submitted,

/s/ *John P. Lavelle, Jr.*
John P. Lavelle, Jr.
john.lavelle@morganlewis.com
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
Tel: 215.963.5000

Counsel for Defendant Philips RS North America LLC

/s/ Michael H. Steinberg
Michael H. Steinberg
SULLIVAN & CROMWELL LLP
1888 Century Park East
Los Angeles, CA 90067
Tel. 310.712.6670
steinbergm@sullcrom.com

Counsel for Defendants Philips North America LLC and Philips Holding USA, Inc.

SERVICE LIST

Michael A. Ponterio, Esq.
Lipsitz, Ponterio & Comerford LLC
424 Main Street, Suite 1500
Buffalo, NY 14202
map@lipsitzponterio.com

Connor G. Sheeman, Esq.
Dunn Sheeman LLP
5910 N. Central Expressway, Suite 1310
Dallas, TX 75206
csheehan@dunnsheehan.com

Attorneys for Plaintiffs Sharon Lis and Allen Lis

Koninklijke Philips N.V.
Philips Center
Amstelplein 2
1096 BC Amsterdam
The Netherlands

Philips Healthcare
222 Jacobs Street
Cambridge, MA 02141

Health System Services, Ltd.
6867 Williams Road
Niagara Falls, NY 14304

U.S. DISTRICT COURT
U.S. District Court, Western District of New York (Buffalo)
CIVIL DOCKET FOR CASE #: 1:23-cv-00907

Lis et al v. Koninklijke Philips N.V. et al
Assigned to:
Cause: 28:1332 Diversity-Product Liability

Date Filed: 08/31/2023
Jury Demand: Both
Nature of Suit: 365 Personal Inj. Prod. Liability
Jurisdiction: Diversity

Plaintiff

Sharon Lis

represented by **Sharon Lis**
PRO SE

Plaintiff

Allen Lis

represented by **Allen Lis**
PRO SE

V.

Defendant

Koninklijke Philips N.V.

Defendant

Philips North America LLC

Defendant

Philips RS North America LLC

represented by **Gary Allyn Adler**
Morgan, Lewis & Bockius LLP
101 Park Avenue
New York City, NY 10178
212-309-6140
Fax: 212-309-6001
Email: gary.adler@morganlewis.com
ATTORNEY TO BE NOTICED

Defendant

Philips Holding USA, Inc.

Defendant

Philips Healthcare

Defendant

Health System Services, Ltd.

Date Filed	#	Docket Text

08/31/2023	1	NOTICE OF REMOVAL by Philips RS North America LLC from Niagara County Supreme Court, case number E180656/2023. (Filing fee $ 402 receipt number ANYWDC-4964324), filed by Philips RS North America LLC. (Attachments: # 1 Exhibit A - Summons and Complaint filed August 10, 2023, # 2 Exhibit B - Notice of Service of Process on Philips North America LLC, # 3 Exhibit C - Notice of Service of Process on Philips North America LLC, # 4 Exhibit D - Notice of Service of Process on Philips Holding USA, Inc., # 5 Exhibit E - Philips RS North America LLC Corporate Records and Business Registrations, # 6 Exhibit F - Philips RS North America Holding Corporation Corporate Records and Business Registrations, # 7 Exhibit G - Philips North America LLC Corporate Records and Business Registrations, # 8 Exhibit H - Philips Holding USA, Inc. Corporate Records and Business Registrations, # 9 Exhibit I - Transfer Order, # 10 Exhibit J - Declaration of William B. Monahan Esq. in Support of Notice of Removal, # 11 Civil Cover Sheet)(Adler, Gary) (Entered: 08/31/2023)
08/31/2023	2	CONTINUATION OF EXHIBITS by Philips RS North America LLC. to 1 Notice of Removal,,,, filed by Philips RS North America LLC. (Adler, Gary) (Entered: 08/31/2023)
08/31/2023	3	NOTICE of Appearance by Gary Allyn Adler on behalf of Philips RS North America LLC (Adler, Gary) (Entered: 08/31/2023)
08/31/2023	4	Corporate Disclosure Statement by Philips RS North America LLC identifying Corporate Parent Philips Holding USA, Inc., Corporate Parent Philips RS North America Holding Corporation, Corporate Parent Koninklijke Philips Naamloze Venootschap for Philips RS North America LLC.. (Adler, Gary) (Entered: 08/31/2023)

PACER Service Center

Transaction Receipt

08/31/2023 14:13:22

PACER Login:	ml001100	**Client Code:**	074058-015802-0738
Description:	Docket Report	**Search Criteria:**	1:23-cv-00907
Billable Pages:	2	**Cost:**	0.20

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

SHARON LIS and ALLEN LIS, *Plaintiffs*, v. KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; PHILIPS RS NORTH AMERICA LLC; PHILIPS HOLDING USA, INC.; PHILIPS HEALTHCARE; and HEALTH SYSTEM SERVICES, LTD., *Defendants*.	CASE NO. _____

NOTICE OF REMOVAL

Defendant Philips RS North America LLC ("Philips RS") (together, with Koninklijke Philips N.V., Philips North America LLC ("Philips NA"), Philips Holding USA, Inc. ("Philips Holding"), and Philips Healthcare, the "Philips Defendants" or "Philips")[1] hereby provides notice pursuant to 28 U.S.C. §§ 1332, 1441, and 1446 of the removal of the above-captioned case from the Supreme Court of the State of New York, County of Niagara, in which it is now pending at Case Number E180656/2023 (the "Underlying Action"), to the United States District Court for the Western District of New York, and states as follows:

[1] All properly joined and served parties consent to removal. As discussed further below, it is not clear which entity Plaintiffs attempt to join by naming "Philips Healthcare" in the Complaint. Nonetheless, as alleged, Philips Healthcare is diverse. Ex. A ¶ 17. As of the filing of this Notice, Koninklijke Philips N.V. has not been served with the Complaint in this action. Plaintiffs' Complaint acknowledges that Koninklijke Philips N.V. is a company established under the laws of The Netherlands, with its principal executive offices in Amsterdam, The Netherlands, and therefore is diverse from Plaintiffs. Ex. A, ¶ 12.

I. INTRODUCTION

1. On August 10, 2023, Plaintiffs Sharon Lis and Allen Lis (together, "Plaintiffs") filed a complaint in the Supreme Court of the State of New York, County of Niagara, Case Number E180656/2023 (the "Complaint"), attached as **Exhibit A, Complaint**.

2. Pursuant to 28 U.S.C. § 1446(a), copies of all process, pleadings, and orders served to date upon Philips RS, including the Complaint, are attached.

3. No other pleadings have been served on Philips RS in this litigation.

4. By filing a Notice of Removal, Philips RS does not waive its right to object to service of process, the sufficiency of process, jurisdiction over the parties, or venue, and Philips RS specifically reserves its right to assert any defenses and objections to which it is entitled.

II. FACTUAL BACKGROUND

5. Plaintiffs allege Philips "develops, manufactures, markets, imports, sells, and distributes a variety of products for sleep and home respiratory care" as well as "a variety of ventilator devices for patients with respiratory conditions." Ex. A, ¶ 2.

6. Plaintiffs allege on June 14, 2021, Philips issued a recall of certain Continuous Positive Airway Pressure ("CPAP"), and Bilevel Positive Airway Pressure ("BiPAP") machines and notified the public of potential serious health risks caused by polyester-based polyurethane sound abatement foam ("PE-PUR foam") used in the design and manufacture of the recalled devices. *Id*. ¶¶ 3-4.

7. Plaintiffs allege PE-PUR foam degradation may have negative health effects, including "acute respiratory distress syndrome (ARDS), lung disease, lung damage, chemical poisoning, heart attack, heart failure, kidney disease, reactive airway disease (RAD), respiratory failure, severe inflammation, and multiple types of cancer." *Id*. ¶ 4.

8. Plaintiff Sharon Lis alleges that on or about April 11, 2018, Health System Services ("HSS") distributed a recalled device (Serial No. J2125235256ED) to her (the "Device"), which she used "on a regular basis from the date she acquired it in early 2018 until approximately June 2021" to treat obstructive sleep apnea. *Id*. ¶ 6.

9. Plaintiff Sharon Lis alleges that, as a result of using the Device, on or about August 11, 2022, she "was diagnosed with bronchogenic carcinoma, a cancerous tumor originating in her lung along the right middle portion of her chest that can only be removed surgically." *Id*. ¶ 7.

10. Plaintiff Sharon Lis allegedly "underwent a right middle lobectomy to remove a section of the carcinoid tumor in her lung," allegedly resulting "in only half of the cancerous tumor being removed due to its location on her lung." *Id*.

11. Plaintiff Sharon Lis as a result allegedly "has suffered and continues to suffer from severe symptoms of lung cancer, requiring continuous medical treatments and resulting in severe associated pain, suffering, and emotional distress." *Id*. ¶ 8.

12. Plaintiff Sharon Lis also alleges she "must have frequent scans of her body and blood work"; that "[s]he is prescribed several pain medications to be able to tolerate the extreme pain that this cancer causes"; that she suffers "from serious and dangerous side effects as a result of the cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, diminished enjoyment of life" and that she "requires lifelong medical treatment and monitoring." *Id*. ¶¶ 9, 10.

13. She asserts causes of action in negligence, *id*. ¶¶ 93-114; strict liability – design defect, *id*. ¶¶ 115-39; strict liability – failure to warn, *id*. ¶¶ 140-71; strict liability – manufacturing defect, *id*. ¶¶ 172-82; fraud and misrepresentation, *id*. ¶¶ 183-97; and breach of warranties, *id*. ¶¶ 198-215, against all Defendants.

14. Plaintiff Allen Lis "brings a derivative claim for loss of consortium arising from injuries relating to those sustained by his lawful spouse, Sharon Lis." *Id*. ¶¶ 83, 216-20.

15. Plaintiffs demand judgment against Defendants "in an amount exceeding the jurisdictional limits of all other courts which would otherwise have jurisdiction over this matter; punitive damages in a sum of money to be determined by the trier of fact; and for such other and further relief as may be just and proper, together with the costs and disbursements of this action." *Id*. ¶ 220.

III. NOTICE OF REMOVAL IS TIMELY

16. Pursuant to 28 U.S.C. § 1446(b)(2)(B), "each defendant shall have 30 days after receipt by or service on that defendant of the initial pleading or summons" to file its notice of removal.

17. Philips North America LLC was served on August 17, 2023 by personal service. **Exhibit B, Service of Philips North America LLC 1; Exhibit C, Service of Philips North America LLC 2**.

18. Philips Holding USA, Inc. was served on August 17, 2023 by personal service. **Exhibit D, Service of Philips Holding USA, Inc. LLC**.

19. Upon information and belief, Koninklijke Philips N.V., Philips RS North America LLC, Philips Healthcare, and Health System Services, Ltd., have not properly been served as of the date of this Notice of Removal.[2]

20. Thus, this notice is timely because it has been filed within thirty days of service on properly joined parties.

[2] As discussed below, service on Health System Services, Ltd., is irrelevant for the purposes of this removal as it is fraudulently joined, and all Philips Defendants consent to the removal.

21. Additionally, this notice is timely because it is filed within one year after commencement of the action pursuant to 28 U.S.C. § 1446(c)(1).

IV. GROUNDS FOR REMOVAL

22. Under 28 U.S.C. § 1441(a), "any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant . . . to the district court of the United States for the district and division embracing the place where such action is pending."

23. This court has original subject-matter jurisdiction under 28 U.S.C. § 1332, diversity jurisdiction, because, excluding the fraudulently joined HSS, this is a civil action between citizens of different states and the amount in controversy exceeds $75,000.

24. While removal is not permitted based only on diversity jurisdiction "if any of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought," 28 U.S.C. § 1441(b)(2), "a plaintiff may not defeat a federal court's diversity jurisdiction and a defendant's right to removal by merely joining as [a] defendant[] [a] part[y] with no real connection with the controversy." *Benihana of Tokyo, LLC v. Angelo, Gordon & Co. L.P.*, 712 Fed. App'x 85, 86 (2d Cir. 2018) (alterations in original) (citation omitted).

25. "Under the doctrine of fraudulent joinder, courts overlook the presence of a non-diverse defendant if there is no possibility, based on the pleadings, that [the] plaintiff can state a cause of action against the non-diverse action in state court." *Id*. (alterations in original) (citations omitted); *see Naber v. First Am. Title Ins. Agency, Inc.*, 2022 WL 16832644, at *4 (W.D.N.Y. Nov. 9, 2022).

26. As discussed below, HSS has been fraudulently joined because Plaintiffs cannot maintain a valid cause of action against it.

27. Therefore, Philips RS may remove the action to federal court pursuant to 28 U.S.C. § 1441(b).

a. <u>There is complete diversity among the properly named parties.</u>

28. Diversity jurisdiction "require[s] complete diversity of citizenship," *i.e.*, "the citizenship of each plaintiff" must be "diverse from the citizenship of each defendant." *Caterpillar Inc. v. Lewis*, 519 U.S. 61, 68 (1996). Accordingly, no plaintiff can be a citizen of the same state as any of the defendants. *See E.R. Squibb & Sons, Inc. v. Accident & Cas. Ins. Co.*, 160 F.3d 925, 930 (2d Cir. 1998); *Boergers v. Miami Dolphins, Ltd.*, 2019 WL 6297203, at *1 (W.D.N.Y. Nov. 25, 2019).

29. The general rule is that diversity is determined at the time the complaint is filed. *Wolde-Meskel v. Vocational Instruction Project Cmty. Servs., Inc.*, 166 F.3d 59, 62 (2d Cir. 1999); *Naber*, 2022 WL 16832644, at *4.

i. <u>Plaintiffs are citizens of New York.</u>

30. Plaintiffs allege they are "citizens of the State of New York, residing in Ontario County." Ex. A ¶ 11.

31. Thus, Plaintiffs are citizens of New York.

ii. <u>Defendant Philips RS is a citizen of Massachusetts and Delaware.</u>

32. Philips RS is a Delaware limited liability company with its principal place of business located in Pennsylvania. **Exhibit F, Philips RS North America LLC Corporate Records & Business Registrations**.

33. As a limited liability company, however, Philips RS is a citizen of the states where its members are citizens for purposes of diversity jurisdiction. *Carter v. HealthPort Techs., LLC*, 822 F.3d 47, 60 (2d Cir. 2016); *Boergers*, 2019 WL 6298203, at *1.

34. Philips RS is wholly owned by a single member, Philips RS North America Holding Corporation, a Delaware corporation with its principal place of business located at 222 Jacobs Street, Cambridge, Massachusetts 02141. **Exhibit G, Philips RS North America Holding Corporation Corporate Records & Business Registrations**.

35. For diversity purposes, a corporation is a citizen of both the state where it is incorporated and the state where it has its principal place of business. 28 U.S.C. § 1332(c)(1).

36. Accordingly, because Philips RS North America Holding Corporation is a citizen of both Delaware and Massachusetts, Philips RS also is a citizen of both Delaware and Massachusetts. Therefore, Philips RS is diverse from Plaintiff.

iii. <u>Defendants Philips North America LLC and Philips Holding USA, Inc. are citizens of Delaware and Massachusetts.</u>

37. Philips North America LLC is a Delaware limited liability company with its principal place of business in Massachusetts. **Exhibit H, Philips North America LLC Corporate Records & Business Registrations**.

38. Philips North America LLC is wholly owned by a single member, Philips Holding USA, Inc., a Delaware corporation with its principal place of business located at 222 Jacobs Street, Cambridge, Massachusetts 02141. **Exhibit I, Philips Holding USA, Inc., Corporate Records & Business Registrations**.

39. Accordingly, because Philips Holding is a citizen of both Delaware and Massachusetts, Philips NA also is a citizen of both Delaware and Massachusetts. Therefore,

Philips NA and Philips Holding are diverse from Plaintiffs. *See Carter*, 822 F.3d at 60 (explaining that an LLC has citizenship of its members); *Boergers*, 2019 WL 6298203, at *1 (same); 28 U.S.C. § 1332(c)(1) (explaining that a corporation is a citizen of the state where it is incorporated and the state of its principal place of business).

iv. Defendant Philips Healthcare is diverse.

40. Plaintiffs name "Philips Healthcare" as a defendant in the Underlying Action. However, without additional information, it is not clear which actual entity Plaintiffs are attempting to join to the Underlying Action by naming "Philips Healthcare" in the Complaint.

41. Nevertheless, even as alleged, the Plaintiffs aver that "Philips Healthcare" is diverse from the Plaintiffs. Ex. A ¶ 17 ("Upon information and belief, Defendant Philips Healthcare is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Cambridge, Massachusetts 02141.").

42. Therefore, based on Plaintiffs' own allegations, "Philips Healthcare" is diverse from Plaintiffs.

v. Defendant HSS is fraudulently joined and thus its citizenship is irrelevant.

43. HSS is fraudulently joined and the Court should ignore its citizenship.

44. To establish that a defendant has been fraudulently joined, the defendant must demonstrate that the plaintiff cannot recover against the non-diverse defendant in state court. *Pampillonia v. RJR Nabisco, Inc.*, 138 F.3d 459, 461 (2d Cir. 1998).

45. The Device was provided pursuant to a physician's prescription. Ex. A, ¶¶ 72, 86, 133, 135, 155-56, 158-61, 164-67, 185, 189, 192, 195-96.

46. The Device can be sold only to physicians or under the prescription of a physician.

47. *First*, Plaintiffs cannot recover against HSS because "[t]he Complaint is devoid of any allegations that [HSS] did anything other than correctly fill a prescription, and dispense the product as packaged by [Philips]." *Negrin v. Alza Corp*., 1999 WL 144507, No. 98 CIV. 4772 DAB (S.D.N.Y. Mar. 17, 1999); *see also Bichler v. Willing*, 58 A.D.2d 331, 397 N.Y.S.2d 57 (1st Dep't 1977) (dismissing claims against non-manufacturer pharmacist where pharmacist did no more than dispense the drug as designed and manufactured by the manufacturer and as prescribed by the physician).

48. In *Negrin*, the plaintiff sued the manufacturers of a nicotine patch for personal injuries, joining the pharmacy that dispensed the product under theories of negligence, breach of warranty, and strict liability. The *Negrin* complaint alleged that the nicotine patch, which required a prescription, was made by the manufacturers and that the patches and their directions were in defective condition when the pharmacy purchased them. The pharmacist merely sold the nicotine patch as packaged by the manufacturer. 1999 WL 144507, at *5.

49. Likewise, in *Winters v. Alza Corp.*, the plaintiff sued the manufacturers of a nicotine patch for wrongful death and asserted tort claims against the pharmacy that dispensed the product. The plaintiff claimed "that his wife's death was the result of a design defect in a pain medication patch manufactured and marketed by two of the defendants" which was "dispensed to [the deceased] in accordance with her doctor's prescription." 690 F. Supp. 2d 350, 351 (S.D.N.Y. 2010).

50. In both *Negrin* and *Winters*, the court held the non-manufacturer party was fraudulently joined, as there was "no possibility" of recovery based on the respective pleadings. *Negrin*, 1999 WL 144507, at *5 ("The Complaint is devoid of any allegations that Duane Reade did anything other than correctly fill a prescription, and dispense that product as packaged by

Defendant Manufacturers. Absent some further allegations, the Court agrees with Defendants that there is no basis under New York law to hold Duane Reade liable on theories of negligence, breach of warranty, or strict liability."); *Winters*, 690 F. Supp. 2d at 353 ("A pharmacist generally cannot be held liable for negligence under New York law in the absence of an allegation that he either (a) failed to fill a prescription precisely as directed or (b) was aware that the customer had a condition rendering prescription of the drug at issue contraindicated.").

51. Similarly, here, there is no possibility of recovery against HSS, the non-manufacturer party. Like the plaintiffs in *Negrin* and *Winters*, Plaintiffs allege that the Philips prescription device at issue was defectively designed and was simply passed through by HSS in filling the prescription in the original packaging without alteration. Ex. A, ¶¶ 2, 3, 21, 54, 85 (alleging ***Philips*** manufactured and designed the Device); *id*. ¶¶ 46 (alleging that ***Philips*** used PE-PUR foam in the Device, ***Philips*** brought the Device to market, ***Philips*** engaged in the FDA's clearance process, and ***Philips*** received complaints about the Recalled Devices); *id*. ¶¶ 48-70 (alleging information regarding the FDA's investigation about ***Philips'*** relationship to the Recalled Devices and the PE-PUR foam); *id*. ¶¶ 115-39 (alleging design defect); *id*. ¶¶ 172-82 (alleging manufacturing defect) *id*. ¶¶ 143, 174 ("The subject device manufactured by Defendants reached Plaintiff Sharon Lis without substantial change."); *id*. ¶¶ 86, 133, 155-56, 158-61, 164-67, 185, 189, 192, 195-96 (alleging Plaintiff Sharon Lis was prescribed the Device).

52. *Second*, HSS is fraudulently joined for the independent reason that Plaintiffs engage in impermissible "group pleading." *See* N.Y. C.P.L.R. § 3013 ("Statements in a pleading shall be sufficiently particular to give the court and parties notice of the transactions, occurrences, or series of transactions or occurrences, intended to be proved and the material elements of each cause of

action or defense."); *Aetna Cas. & Sur. Co. v. Merchs. Mut. Ins. Co.*, 84 A.D.2d 736, 736 (1st Dep't 1981); *Barlow v. Skroupa*, 173 N.Y.S.3d 98 (N.Y. Cty. Mar. 23, 2022) (dismissing unjust enrichment claims where "plaintiffs . . . rest on their impermissible group pleading") (citation omitted); *see also Negrin*, 1999 WL 144507, at *5 (finding fraudulent joinder where, aside from an allegation that the nicotine patches and directions "were purchased new from the defendant [pharmacy] and were in defective condition at that time," there were "no further factual allegations regarding specific actions taken by [the pharmacy]" and "the remainder of the [c]omplaint alleges that 'defendants' engaged in the same conduct").

53. In *Aetna Casualty & Surety Co.*, the court held that because "the first four causes of action are pleaded against all defendants collectively without any specification as to the precise tortious conduct charged to a particular defendant . . . Defendants cannot reasonably be required to frame a response to the complaint in its present state." 84 A.D.2d at 736.

54. Here, as in *Aetna*, *Barlow*, and *Negrin*, Plaintiffs engage in impermissible group pleading. Plaintiffs make only a handful of allegations against HSS individually, which primarily relate to HSS's citizenship and the appropriateness of the Court's jurisdiction. *See* Ex. A, ¶¶ 18, 33, 39, 40. Plaintiffs purport to make substantive allegations against HSS only in two paragraphs: first, Plaintiffs allege, in a conclusory manner, that "the subject device used by Plaintiff Sharon Lis was distributed by HSS" on or about April 11, 2018, Ex. A ¶ 6; second, Plaintiffs allege, again in a conclusory manner, that HSS "was engaged in the business of distributing, selling, promoting, advertising and marketing the subject device," Ex. A ¶ 33.

55. Throughout the remainder of the Complaint, Plaintiffs attempt to evade scrutiny by directing nearly all of their allegations either to the Philips Defendants or at "Defendants" generally.

56. Moreover, Plaintiffs do not, at any point, attempt to allege that "HSS" is involved in the development, design, or manufacture of the subject devices—nor could they in good faith. Yet, throughout their recitation of their causes of action, Plaintiffs lump all "Defendants" together when alleging they "designed and developed" and "manufactured" the recalled devices and the subject device. *See, e.g.*, *id*. ¶¶ 95, 96, 143-45, 176. Any attempt to attribute these functions to HSS is misleading and false, as demonstrated by Plaintiffs' express allegations that the Device at issue is a "***Philips*** DreamStation Auto Continuous Positive Airway Pressure mechanical ventilator device." *Id.* ¶ 1 (emphasis added). Plaintiffs' allegations against "Defendants" as a group apply only to the Philips Defendants, and any attempted application to HSS should be disregarded.

57. Moreover, throughout the Complaint, Plaintiffs make allegations against "Defendants" as a group without thought or consideration as to which acts relate to which Defendants. For example, Plaintiffs allege that "Defendants acted in all respects as agents or apparent agents of one another" and "Defendants combined their property and labor in a joint undertaking for profit, with rights of mutual control over each other." *Id*. ¶ 35. These allegations plainly concern the Philips Defendants, not an ultimate, third-party retailer like HSS.

58. It is clear that when Plaintiffs refer to "Defendants" collectively, they intend to, and plausibly only, address the Philips Defendants.

59. Because Plaintiffs' allegations are directed broadly to "Defendants" even though they plainly and plausibly relate only to the Philips Defendants, they should be disregarded as "group pleadings" that are too general to survive New York's pleading standard. *See* N.Y. C.P.L.R. § 3013; *Aetna*, 84 A.D.2d at 736; *Barlow*, 173 N.Y.S.3d at 108; *Negrin*, 1999 WL 144507, at *5.

60. Accordingly, HSS's citizenship is of no consequence as it is fraudulently joined

because Plaintiffs cannot state a basis for recovery under state law. *See Pampillonia*, 138 F.3d at 462; *Naber*, 2022 WL 16832644, at *4; *Negrin*, 1999 WL 144507; *Winters*, 690 F. Supp. 2d at 350.

vi. <u>There is complete diversity between the properly joined parties.</u>

61. Thus, based on the foregoing, there is complete diversity between the properly joined parties:

<u>Plaintiff</u>	<u>Defendants</u>
Sharon Lis (NY) Allen Lis (NY)	Philips RS (DE/MA) Philips North America (DE/MA) Philips Holding USA, Inc. (DE/MA) Philips Healthcare (DE/MA)

b. <u>The amount in controversy requirement is satisfied.</u>

62. There plainly is more than $75,000 in controversy. *See* 28 U.S.C. § 1332(a).

63. Plaintiffs do not explicitly plead in the Complaint that the amount in controversy exceeds $75,000.[3] Given the nature and extent of Plaintiffs' alleged injuries and harm, however, the amount in controversy plainly exceeds the jurisdictional threshold.

64. Although Philips RS denies any liability to Plaintiffs, the nature of the case (a medical device products liability action), the harms alleged (bronchogenic carcinoma, surgery, "severe symptoms of lung cancer," continuous/lifelong medical treatments, "severe associated pain, suffering, and emotional distress," "diminished enjoyment of life," and loss of consortium), and the nature of the damages requested (including not only what appear to

[3] Plaintiffs demand damages against Defendants "in an amount exceeding the jurisdictional limits of all other courts which would otherwise have jurisdiction over this matter." Ex. A, ¶ 113.

be compensatory damages, but also punitive damages, and "costs and disbursements") place far more than $75,000 in controversy.

65. "[A] defendant's notice of removal need include only a plausible allegation that the amount in controversy exceeds the jurisdictional threshold." *Dart Cherokee Basin Operating Co., LLC v. Owens*, 574 U.S. 81, 89 (2014); *Jean-Louis v. Carrington Mortg. Servs., LLC*, 849 F. App'x 296, 299 n.11 (2d Cir. 2021); *Fibrix LLC v. Schlumberger Tech. Corp.*, 2022 WL 18215855, at *3 (W.D.N.Y. Nov. 2, 2022).

66. Where the complaint does not specify the amount in controversy, "courts examine the nature of the claims [and] factual allegations within the pleadings" to determine whether the jurisdictional threshold is satisfied. *Burr ex rel. Burr v. Toyota Motor Credit Co*., 478 F. Supp. 2d 432, 438 (S.D.N.Y. 2006) (citations omitted).[4]

67. In *In re Eliquis (Apixaban) Prod. Liab. Litig.*, three plaintiffs filed motions to remand and argued that the amount in controversy requirement was not satisfied. No. 17MD2754 (DLC), 2018 WL 1394179, at *1-2 (S.D.N.Y. Mar. 19, 2018). The court disagreed and held that the amount in controversy was satisfied because "on their face, the complaints establish a reasonable probability that the claims seek damages in excess of $75,000." *Id*. at *2. Plaintiffs each alleged serious injury resulting from their use of the product at issue and sought damages for their physical injuries as well as pain and suffering, loss of income, and attorneys' fees. *Id*.

[4] *See Short v. Conagra Foods, Inc.*, No. CIV.A. 5:08-112-JMH, 2008 WL 2559244, at *2 (E.D. Ky. June 23, 2008) ("Noting Plaintiff's allegation of permanent loss of bodily function and great pain, along with the numerous other cases in this MDL in which the damages exceed $75,000, this Court is of the opinion that Defendant has met its burden of showing that it is 'more likely than not' that the jurisdictional amount in controversy prerequisite is met in this case.")

68. In *Nickel v. Nike, Inc.*, the plaintiff brought a personal injury action alleging severe and permanent injury in addition to mental anguish, and alleged that he "has been caused to incur, and will continue to incur, expenses for medical care and attention; and as a further result, Plaintiff was, and will continue to be, rendered unable to perform Plaintiff's normal activities and duties." No. 11 CIV. 4495 PKC, 2011 WL 4343852, at *2 (S.D.N.Y. Aug. 18, 2011). The court concluded that "these allegations of serious, permanent, and debilitating physical and mental injury support the conclusion that there is a reasonable probability that the $75,000 threshold will be satisfied." *Id.*; *see also Juarbe v. Kmart Corp.*, No. 05CIV1138TPGTS, 2005 WL 1994010, at *1-2 (S.D.N.Y. Aug. 17, 2005) (finding amount in controversy satisfied in personal injury case where plaintiff alleged serious and permanent injury, pain and suffering, past and future medical expenses and diminished lifestyle); *Felipe v. Target Corp.*, 572 F. Supp. 2d 455, 459 (S.D.N.Y. 2008) (same and citing *Juarbe,* 2005 WL 1994010, at *1-2); *Burr ex rel. Burr*, 478 F. Supp. 2d at 439 (finding amount in controversy satisfied in personal injury case where plaintiff alleged "serious and severe permanent personal injuries").

69. In *Taylor v. Medtronic, Inc.*, the plaintiff alleged "constant pains, lump in lower right abdomen, significant weight loss, worsening lower back pain, trauma to [his] abdomen and thereafter severe emotional distress, extreme pain and discomfort, and superior mesenteric artery syndrome, and that he will likely undergo further medical treatment and procedures as a result of his hernia repair surgery and implanted mesh." No. 318CV1201FJSML, 2020 WL 886118, at *4 (N.D.N.Y. Feb. 24, 2020), remanded on other grounds, 15 F.4th 148 (2d Cir. 2021) (citations omitted). In *Taylor*, the plaintiff sought "damages including medical expenses, hospitalization expenses, lost income, physical and

mental pain, and other economic and non-economic damages, including punitive damages." *Id*. The Court found that, based on these injuries, the amount in controversy was satisfied.

70. In the Underlying Action, Plaintiffs also bring a products liability action, also allege serious injuries (including cancer), severe and permanent injury, mental pain and suffering, damages for past and future medical expenses and diminished lifestyle, among other alleged injuries and damages, under similar causes of action. Therefore, the Court should find the amount in controversy is satisfied.

71. Additionally, punitive damages, which Plaintiffs request, may be considered when calculating the amount in controversy. *Freeman v. Jacobson*, No. 20-CV-10040 (SN), 2021 WL 3604754, at *4 (S.D.N.Y. Aug. 13, 2021) ("The Court may consider punitive damages in addition to compensatory damages to calculate the amount in controversy.") (citing *A.F.A. Tours, Inc. v. Whitchurch*, 937 F.2d 82, 87 (2d Cir. 1991)).

72. For these reasons, the amount in controversy requirement clearly is satisfied.[5]

[5] Other courts are in agreement that allegations such as those advanced by Plaintiffs here satisfy the amount in controversy requirement. *See Smith v. Wyeth Inc.*, 488 F. Supp. 2d 625, 630 (W.D. Ky. May 11, 2007) (denying remand and finding allegations "likely amount to claims in excess of $75,000" where plaintiff sought to recover for a permanent injury, as well as pain and suffering, punitive damages, and past and future medical expenses); *Milter v. Wright Medical Group, Inc.*, 11-CV-11353, 2011 WL 4360024, at *3 (E.D. Mich. Sept. 19, 2011) (denying remand and finding "no doubt" that plaintiff's alleged injuries "more likely than not" exceeded $75,000 where plaintiff alleged that a medical device manufactured by defendants was defective, requiring plaintiff to incur revision surgery, hospitalization, elevated levels of toxic metals in plaintiff's blood, disability, medical expenses, lost wages, and physical and mental pain and suffering); *Culpepper v. Stryker Corp*., 968 F. Supp. 2d 1144, 1158 (M.D. Ala. 2013) (noting generally that product liability actions routinely result in verdicts in excess of $75,000); *Evans v. CDX Services, LLC*, 528 F. Supp. 2d 599, 606 (S.D.W. Va. Jan. 4, 2007) (concluding that "one can easily conclude the amount in controversy is satisfied" in the context of a tort where plaintiff alleges "serious bodily injury, tremendous pain and suffering, loss of earning capacity," and "loss of ability to enjoy life"); *Fuller v. Pistorius Mach. Co.,* No. 05-6099-CV-W-FJG, 2006 WL 8438334, at *1-2 (W.D. Mo. July 21, 2006) (denying remand and finding amount in controversy satisfied in a products liability action alleging permanent injuries and damages for "for medical care and treatment, surgery and therapy, and . . . lost wages and . . . earnings capacity" because plaintiff "alleged in his petition a serious and disabling injury").

V. VENUE

73. This lawsuit may be removed to the United States District Court for the Western District of New York, pursuant to 28 U.S.C. §§ 1332(a)(1) and 1441(a).

74. The United States District Court for the Western District of the New York is the federal judicial district encompassing the Supreme Court of the State of New York, County of Niagara. 28 U.S.C. § 112(d).

75. On October 8, 2021, the United States Judicial Panel on Multidistrict Litigation issued a Transfer Order, consolidating related class action cases and individual personal injury cases like this matter into a multidistrict litigation (MDL 3014) and ordering their transfer to the Western District of Pennsylvania, before the Honorable Joy Flowers Conti (the "MDL") for coordinated or consolidated pretrial proceedings. **Exhibit J, Transfer Order**.

76. It is anticipated that this case will be transferred to the MDL following removal.

VI. CONSENT

77. Each defendant that has been properly joined and served consents to removal as required by 28 U.S.C. § 1446(b)(2). **Exhibit K, Declaration of W. Monahan**.

VII. PROCEDURE

78. Written notice of the filing of the Notice of Removal will be promptly served on all other parties to this action and a copy will promptly be filed with the Supreme Court of the State of New York, Country of Niagara, as required by 28 U.S.C. § 1446(d).

79. Included with this Notice of Removal is the filing fee required by 28 U.S.C. § 1914.

VIII. CONCLUSION

Philips RS respectfully removes this action from the Supreme Court of the State of New York, Country of Niagara to the United States District Court for the Western District of New York.

Respectfully submitted,

/s/ Gary A. Adler

John P. Lavelle, Jr.
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: +1.215.963.5000
Facsimile: +1.215.963.5001
john.lavelle@morganlewis.com

Of Counsel for Defendant Philips RS North America LLC

Gary A. Adler
MORGAN, LEWIS & BOCKIUS LLP
101 Park Ave.
New York, NY 10178-0060
Telephone: +1.212.309.6140
Facsimile: +1.212.309.6001
gary.adler@morganlewis.com

Attorneys for Defendant Philips RS North America LLC

Dated: August 31, 2023

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on August 31, 2023, I caused a true and exact copy of the foregoing document to be served via email and first-class mail to counsel of record as follows:

Michael A. Ponterio, Esq.
Lipsitz, Ponterio & Comerford LLC
424 Main Street, Suite 1500
Buffalo, NY 14202
Telephone: +1.716.849.0701
Fax: +1.716.849.0708

Connor G. Sheehan, Esq.
Texas Bar No. 24046827
Dunn Sheehan LLP
5910 N. Central Expressway, Suite 1310
Dallas, Texas 75206
Telephone: +1.214.866.0077
Fax: +1.214.866.0070
csheehan@dunnsheehan.com

Counsel for Plaintiffs

/s/ Gary A. Adler

EXHIBIT A

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NIAGARA

SHARON LIS and
ALLEN LIS, her spouse
5384 County Road 36
Honeoye, NY 14471

Plaintiffs,

vs.

KONINKLIJKE PHILIPS N.V.
Philips Center
Amstelplein 2,
1096 BC Amsterdam
The Netherlands

PHILIPS NORTH AMERICA LLC
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

PHILIPS RS NORTH AMERICA LLC
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

PHILIPS HOLDING USA, INC.
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

PHILIPS HEALTHCARE
222 Jacobs Street
Cambridge, MA 02141

HEALTH SYSTEM SERVICES, LTD.
6867 Williams Road
Niagara Falls, NY 14304

Defendants.

SUMMONS

Plaintiffs designate Niagara County as the place of trial

The basis of venue is the residence of a defendant

Defendant, Health System Services, Ltd., resides at 6867 Williams Road Niagara Falls, NY

County of Niagara

TO THE ABOVE-NAMED DEFENDANTS:

YOU ARE HEREBY SUMMONED to answer the Verified Complaint in this action and to serve a copy of your answer, or, if the Verified Complaint is not served with this Summons, to

serve a notice of appearance on the Plaintiffs' Attorneys within 20 days after the service of this Summons, exclusive of the day of service (or within 30 days after the service is complete if this Summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the Verified Complaint.

Dated: Buffalo, New York
August 10, 2023

Michael A. Ponterio, Esq.
Lipsitz, Ponterio & Comerford, LLC
424 Main Street, Suite 1500
Buffalo, NY 14202
Phone: 716.849.0701
Fax: 716.849.0708

Connor G. Sheehan*
Texas Bar No. 24046827
csheehan@dunnsheehan.com
DUNN SHEEHAN LLP
5910 N. Central Expressway, Suite 1310
Dallas, Texas 75206
Phone: 214.866.0077
Fax: 214.866.0070
**pro hac vice application forthcoming*

Attorneys for Plaintiffs

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NIAGARA

SHARON LIS and
ALLEN LIS, her spouse,

Plaintiffs,

VERIFIED COMPLAINT

vs.

KONINKLIJKE PHILIPS N.V.,
PHILIPS NORTH AMERICA LLC,
PHILIPS RS NORTH AMERICA LLC,
PHILIPS HOLDING USA, INC.,
PHILIPS HEALTHCARE,
HEALTH SYSTEM SERVICES, LTD.,

Defendants.

Plaintiffs SHARON LIS and ALLEN LIS ("Plaintiffs"), by and through their counsel, file this Verified Complaint against Defendants KONINKLIJKE PHILIPS N.V. ("Royal Philips"), PHILIPS NORTH AMERICA LLC ("Philips NA"), PHILIPS RS NORTH AMERICA LLC ("Philips RS"), PHILIPS HOLDING USA, Inc. ("PHUSA"), PHILIPS HEALTHCARE ("PHC" and, collectively with Royal Philips, Philips NA, Philips RS, and PHUSA, "Philips"), and HEALTH SYSTEM SERVICES, LTD. ("HSS" and, collectively with Philips, "Defendants").

INTRODUCTION

1. Plaintiff Sharon Lis ("Sharon") brings this action on behalf of herself for personal injuries that she sustained as a purchaser and long-time user of a defective Philips DreamStation Auto Continuous Positive Airway Pressure mechanical ventilator device (the "DreamStation CPAP machine" or "subject device") that contains polyester-based polyurethane sound abatement foam ("PE-PUR Foam"). On June 14, 2021, Phillips recalled the DreamStation CPAP machine due to the PE-PUR Foam's known propensity to break down, resulting in small pieces of foam and invisible chemicals being breathed in or swallowed by the user resulting in serious and permanent

injuries. Plaintiff Allen Lis ("Allen") brings a derivative claim for loss of consortium arising from injuries relating to those sustained by his lawful spouse, Sharon.

2. Philips develops, manufactures, markets, imports, sells, and distributes a variety of products for sleep and home respiratory care. Philips also develops, manufactures, markets, imports, sells, and distributes a variety of ventilator devices for patients with respiratory conditions.

3. On April 26, 2021, Philips publicly announced its determination that there were risks that the PE-PUR Foam used in certain CPAP, Bi-Level PAP, and mechanical ventilator devices manufactured by Philips – specifically including the subject device used by Sharon – will degrade or off-gas under certain circumstances.

4. On June 14, 2021, Royal Philips issued a recall ("Recall Notice") in the United States of its CPAP, Bi-Level PAP, and mechanical ventilator devices containing PE-PUR Foam – specifically including the subject device. In particular, Philips disclosed for the first time its determination that (a) the PE-PUR Foam in those devices emits volatile organic compounds which, when inhaled, can result in serious adverse health effects, including but not limited to acute respiratory distress syndrome (ARDS), lung disease, lung damage, chemical poisoning, heart attack, heart failure, kidney disease, reactive airway disease (RAD), respiratory failure, severe inflammation, and multiple types of cancer.

5. In total, Philips announced that "between 3 million and 4 million" devices were targeted in the recall. In its Recall Notice, Philips advised of serious health risks related to the PE-PUR Foam and recommended that patients using the recalled CPAP and Bi-Level PAP devices immediately discontinue use of the devices and consult with their physicians regarding alternative ventilator options.

6. On or about April 11, 2018 – more than three years before Philips issued the Recall Notice – the subject device used by Plaintiff Sharon Lis was distributed by HSS. This device, the Philips' subsequently-recalled devices, the DreamStation CPAP Machine, Serial No. J2125235256ED, was used by Plaintiff Sharon Lis to treat her obstructive sleep apnea. Sharon, a 55-year-old lifetime nonsmoker, used the CPAP device on a regular basis from the date she acquired it in early 2018 until approximately June 2021.

7. On or about August 11, 2022, as a result of her extended usage of the subject device, Sharon was diagnosed with bronchogenic carcinoma, a cancerous tumor originating in her lung along the right middle portion of her chest that can only be removed surgically. On or about November 2, 2022, Sharon underwent a right middle lobectomy to remove a section of the carcinoid tumor in her lung. The surgery resulted in only half of the cancerous tumor being removed due to its location on her lung.

8. As a direct and proximate result of her long-term use of Defendants' defective and dangerous device, Sharon has suffered and continues to suffer from severe symptoms of lung cancer, requiring continuous medical treatments and resulting in severe associated pain, suffering, and emotional distress.

9. Among other things, Sharon must have frequent scans of her body and blood work to determine if the cancer has grown or spread, which will result in a second surgery to remove the remainder of her cancerous lung. She is prescribed several pain medications to be able to tolerate the extreme pain that this cancer causes.

10. As a direct and proximate result of Defendants' wrongful conduct alleged herein, Sharon has suffered, continues to suffer, and will for the foreseeable future suffer from serious and dangerous side effects as a result of the cancer, as well as other severe and personal injuries which

are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and requires lifelong medical treatment and monitoring.

PARTIES

11. Plaintiffs are citizens of the State of New York, residing in Ontario County. Plaintiff Allen Lis is the lawful wedded spouse of Plaintiff Sharon Lis.

12. Upon information and belief, Defendant Royal Philips is a public limited liability company established under the laws of The Netherlands, having its principal executive offices at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the parent company of Philips North America, LLC and Philips RS North America, LLC.

13. Upon information and belief, Royal Philips controls Philips NA and Philips RS in the manufacturing, selling, distributing and supplying of the recalled CPAP, Bi-Level PAP and mechanical ventilator devices, including but not limited to the DreamStation CPAP Machine used by Plaintiff.

14. Upon information and belief, Defendant Philips NA is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly owned subsidiary of Royal Philips.

15. Upon information and belief, Defendant Philips RS is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS is a wholly owned subsidiary of Royal Philips. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.

16. Upon information and belief, Defendant PHUSA is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. PHUSA is a wholly owned subsidiary of Royal Philips.

17. Upon information and belief, Defendant Philips Healthcare is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Cambridge, Massachusetts 02141. That at all times hereinafter mentioned, it has been engaged in the sale, distribution and marketing of medical equipment including, but not limited to, the Philips DreamStation CPAP machine.

18. Upon information and belief, that at all times hereinafter mentioned, the Defendant, Health System Services, Ltd., was and still is a New York domestic business corporation duly organized under §402 of New York State Business Corporation Law. That at all times hereinafter mentioned, the Defendant, Health System Services, Ltd., has its principal place of business in Niagara Falls, New York. Venue is in Niagara County pursuant to CPLR 503 based upon Defendant, Health System Services, Ltd.'s principal place of business located at 6867 Williams Road, Niagara Falls, New York 14304, Niagara County.

JURISDICTION AND VENUE

19. Upon information and belief, at all relevant times, Defendant Royal Philips conducted business in the State of New York; transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; derived substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury to a person or property with the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

20. Upon information and belief, at all relevant times, Defendant Royal Philips shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times, Defendant Royal Philips was engaged in the business of designing, manufacturing, distributing, selling and marketing the subject device.

21. Upon information and belief, at all relevant times, Defendant Royal Philips NA transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; manufactured, distributed, designed and sold, the subject device with the serial number J2125235256ED.

22. Upon information and belief, at all relevant times, Defendant Philips NA is a Delaware corporation with its principal place of business located in Cambridge, Massachusetts. Defendant Philips NA is a wholly owned subsidiary of Defendant Royal Philips. Upon information and belief, Defendant Philips NA manages the operation of Defendant Royal Philips' various lines of business, including Philips RS. The sole member of Defendant Philips NA is Defendant PHUSA, which is a Delaware corporation with its principal place of business place of business in Cambridge, Massachusetts.

23. Upon information and belief, at all relevant times, Defendant Philips NA did business and contracted to supply goods or services in the State of New York; derived substantial profits from its sales in the State of New York; and committed a tortious act within the State of New York causing injury to a person or property within the State of New York.

24. Upon information and belief, at all relevant times, Defendant Philips NA was engaged in the business of designing, manufacturing, distributing, selling and marketing the subject device; shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce; transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302

25. Upon information and belief, at all relevant times, Defendant PHUSA is a Delaware corporation with its principal place of business in Cambridge, Massachusetts. Defendant PHUSA is a holding company that is the sole member of Defendant Philips NA.

26. Upon information and belief, at all relevant times, Defendant PHUSA shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times, Defendant PHUSA transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; derived substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury to a person or property with the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

27. Upon information and belief, at all relevant times, Defendant Philips RS is a Delaware corporation with its principal place of business in Pittsburgh, Pennsylvania. Defendant Philips RS was formerly operated under the business name Respironics, Inc. Defendant Royal Philips acquired Respironics, Inc. in 2008.

28. Upon information and belief, at all relevant times, Defendant Philips RS shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times, Defendant Philips RS was engaged in the business of designing, manufacturing, distributing, selling and marketing the subject device.

29. Upon information and belief, at all relevant times, Defendant Philips RS transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; did business in the State of New York; derived substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury

to a person or property within the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

30. Upon information and belief, at all relevant times, Defendant PHC is a Delaware company with its principal place of business in Cambridge, Massachusetts. At all relevant times, Defendant PHC was a foreign corporation, organized and existing pursuant to and by virtue of the laws of the State of Delaware that has authorization to do business in the State of New York.

31. Upon information and belief, at all relevant times, Defendant PHC shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times herein, Defendant PHC was engaged in the business of distributing, selling, promoting, advertising and marketing the subject device.

32. Upon information and belief, at all relevant times, Defendant PHC was and still is a corporation conducting business in the State of New York; Defendant PHC transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; derived substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury to a person or property within the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

33. Upon information and belief, Defendant HSS is a New York company with its principal place of business in Niagara Falls, New York. Defendant HSS distributed, shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times, Defendant HSS was engaged in the business of distributing, selling, promoting, advertising and marketing the subject device; was and still is a corporation conducting business in the State of New York; contracted to supply goods or services in the State of New York; derived

substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury to a person or property with the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

34. Upon information and belief, at all relevant times, Defendants (other than HSS) were the mere alter egos or instrumentalities of each other. There is such a unity of interest and ownership between Defendants that the separate personalities of their entities ceased to exist. Defendants (other than HSS) operated as a single enterprise, equally controlled each other's business affairs, commingled their assets and funds, disregarded corporate formalities and used each other as a corporate shield to defeat justice, perpetuate fraud and evade contractual and/or tort liability.

35. Upon information and belief, at all relevant times, Defendants acted in all respects as agents or apparent agents of one another. Upon information and belief, at all relevant times, Defendants acted in concert in the designing, manufacturing, marketing, promoting, advertising and selling of devices for the treatment of obstructive sleep apnea, including the subject device. Defendants combined their property and labor in a joint undertaking for profit, with rights of mutual control over each other, rendering them jointly liable to Plaintiffs.

36. Upon information and belief, Defendants' actions in marketing, distributing and selling their devices in New York should have led them to reasonably anticipate being brought into Court in New York.

37. Upon information and belief, Defendants have sufficient "minimum contacts" with New York that subjecting them to personal jurisdiction in New York does not offend traditional notions of fair play and substantial justice.

38. As detailed below, upon information and belief, Plaintiff Sharon Lis, age 55, suffered injuries from the subject device that Defendants negligently designed and/or

manufactured, sold and distributed. Thus, Defendants committed a tort in New York that caused injuries in New York and the Court has personal jurisdiction over Defendants under New York State's Long Arm Statute.

39. Upon information and belief, this Court has personal jurisdiction over Defendants Royal Philips, Philips NA, Philips RS, PHUSA, PHC and HSS because of their systematic and continuous contacts with New York as well as their maintenance of a registered agent for service of process in New York. Federal diversity jurisdiction does not exist because Defendant HSS is a resident and corporate citizen of New York with its headquarters located in Niagara County, New York.

40. This Court is a proper venue for this civil action because Defendant HSS has its principal place of business in Niagara County at 6867 Williams Road, Niagara Falls, New York and committed the tortious acts at issue in this Complaint in Niagara County, New York and other locations in New York. This Court's exercise of personal jurisdiction over Defendants comports with due process.

FACTUAL ALLEGATIONS

The Philips DreamStation CPAP Machine

41. Obstructive sleep apnea ("OSA") is a sleeping disorder in which breathing is disrupted temporarily during sleep periods when breathing stops or becomes very shallow. OSA is associated with fatigue, daytime sleepiness, interrupted sleep, or snoring, among other symptoms.

42. CPAP therapy helps treat sleep apnea by preventing the person's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

43. Bi-PAP therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air pressure in an individual's airway.

44. At all relevant times, Defendants developed, manufactured, marketed, sold, and distributed a lineup of CPAP and BiLevel PAP devices under the Philips "Sleep & Respiratory Care" portfolio. These devices are designed to assist individuals with a number of sleep, breathing and other respiratory conditions, including OSA.

45. Philips' flagship CPAP/BiPAP machine product family is known as the "DreamStation" family line, which includes the original DreamStation, launched in October 2015 and the DreamStation Go (a travel version). Phillips sold DreamStation products through its subsidiary Respironics, that Philips acquired in 2008.

46. Philips used PE-PUR Foam in the subject device even though it was widely known that this foam is susceptible to hydrolysis.[1] Philips brought the subject device to market through the FDA's 510(k) clearance process, which is less stringent than the FDA's Pre-Market Approval ("PMA") application process. Having placed the subject device on the market, Philips assumed various duties under federal and state law, including the duty to investigate complaints and injuries and report adverse events. Philips sold the subject device as a "clinically proven" treatment for sleep disorders, exposing users of the subject device such as Sharon at the known (to Defendants) and undisclosed risk of serious and debilitation injury. The subject device failed to comply with "current good manufacturing practice" requirements ("GMPs") and other obligations imposed by FDA regulations. For example, the PE-PUR Foam in the subject device degrades and exposes patients to toxic particles and VOCs, some of which are known or suspected carcinogens.

[1] Poly*ether* polyurethan foam, which is less prone to hydrolysis, was an available safer alternative.

47. Since 2008, Philips has received hundreds of thousands of complaints of foam degradation in the subject devices. Instead of acting, Philips turned a blind eye to the problem and actively concealed it.

Philips Knew Of The Dangers Of Pe-Pur Foam Since At Least 2015

48. In 2021, an FDA investigation concluded that Philips knew as early as 2015 – *i.e.*, three years before Sharon acquired the DreamStation CPAP machine that ultimately caused her cancer – that Defendants' CPAP machines were unsafe:

> Beginning in 2015, Philips received data from a variety of sources regarding degradation of the PE-PUR foam contained within the recalled devices, including complaints, test reports, information from suppliers, and information from another entity owned by Philips' parent company. Philips failed to adequately evaluate this data and incorporate it into its CAPA [Corrective and Preventive Actions] system for further investigation and potential mitigation, as required by current good manufacturing practice requirements codified in 21 C.F.R. § 820.100.[2]

49. The FDA's determination was based in part on twenty-one (21) site inspections of Philips' Murrysville, Pennsylvania facility between August 26, 2021, and November 9, 2021. The lead FDA investigator, Katelyn A. Staub-Zamperini, memorialized the agency's finding in a 28-page FDA, 483 Report issued on November 9, 2021.[3]

50. In connection with its investigation, the FDA learned that Philips had received numerous complaints from customers about degradation of the foam in its Recalled Devices from at least as early as 2008:

> [A] query of your firm's consumer complaints from 01/01/2008 to current, for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black, **resulted in over 222,000 complaints, and over 20,000 of which occurred between 2008 to 2017 and involved Trilogy devices.** Additionally, your firm performed a foam related complaint data analysis in April 2021 on complaints confirmed to be related to or involve foam degradation issues. The raw complaint data documents that **30 Trilogy related complaints were received from 2014 to**

[2] https://www.fda.gov/media/158129/download (last accessed June 16, 2022) ("518(b) Notice"), at 6.
[3] A 483 Report is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. A redacted version of the 483 report is available here: https://www.fda.gov/media/l 54244/download (last accessed June I6, 2022).

2017, and 1,254 related complaints were received across all products containing the affected foam, from 2014 to 2021.[4]

51. The FDA also concluded that "[n]o formal investigation, risk analysis, or CAPA[5] were initiated, performed, or documented [by or on behalf of Philips], in response to the at least 222,000 complaints that could potentially be related to foam degradation and received from 2008 to 2017."[6] Further, the FDA determined that Philips "was made aware of polyester polyurethane foam degradation issues in/around October 2015 . . ."[7]

52. The FDA also found that Philips' analysis of consumer complaints was defective in that it "was not adequately performed to identify or detect quality problems";[8] that "potential foam degradation in Trilogy ventilator devices is not an isolated incident, and you [Philips] also have not documented a detailed rationale for why harm is not likely to occur again, as required by your Health Hazard Evaluation's instructions";[9] and that Philips' "risk analysis is inadequate or was not performed when appropriate or within an appropriate time frame of your firm becoming aware" of these issues.[10]

53. On May 2, 2022, the FDA issued a formal notice to Philips pursuant to Section 518(b) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360h(b) (the "518(b) Notice").[11]

54. The 518(b) Notice stated that "there is sufficient evidence for FDA to determine that the devices subject to the recall present an unreasonable risk of substantial harm to the public health" and "that there are reasonable grounds to believe that the recalled devices that Philips

---

[4] 483 Report at 12 (emphasis added).
[5] A Corrective and Preventative Action ("CAPA") refers to procedures that medical device manufactures must follow to identify and attempt to correct when a quality problem is detected. *See* 21 C.F.R. § 820.100.
[6] *Id.* at 16.
[7] 483 Report at 18.
[8] 483 Report at 16.
[9] *Id.* at 13.
[10] *Id.* at 3.
[11] https://www.fda.gov/media/158129/download (last accessed June 16, 2022).

manufactured after November 2015 were not properly manufactured with reference to the state of the art as it existed at the time of the devices' manufacture."[12]

55. The FDA also concluded that "[t]his risk is not the unavoidable byproduct of current ventilator, CPAP machine, and BiPAP machine technologies. Indeed, Philips and its competitors market ventilators, CPAP machines, and BiPAP machines that do not use PE-PUR Foam."[13]

56. The FDA's findings are directly applicable to the Philips DreamStation CPAP machine that caused Sharon's lung cancer.

57. Knowing about these safety issues with the PE-PUR Foam, Philips tested the foam material used in its Recalled Devices. According to the FDA, "this testing spoke only to the limited finding that in the case of the [redacted] foam samples 'returned from service in a Pacific rim location,' spectroscopy results were 'consistent with an environmental/chemical exposure causing base polymer cleavage and embrittlement of the material."[14] Nonetheless, based on the results of this limited testing, Philips concluded that no escalation to a CAPA process was required.

58. Philips was alerted to more warning signs of the dangers of the subject device as it continued to ask its supplier about the properties of the PE-PUR Foam it was continuing to put in medical devices that millions of its customers, including Sharon, were breathing through nightly to help their sleeping disorders with no way to know that they were exposing themselves to deadly respiratory conditions and cancers.

Philips Opened An Internal Investigation Into Foam Degradation In Mid-2018

59. On April 12, 2018, almost to the day when Sharon acquired and began to use the subject device, Philips opened a precursor to a formal CAPA, referred to by Philips as a CAPA

[12] *Id.* at 2.
[13] *Id.* at 6
[14] 518(b) Notice at 7.

INV 0988, "to investigate complaints related to potential foam degradation for the Trilogy devices in Australia and to determine what actions should be taken."[50]

60. On June 20, 2018, Philips closed CAPA INV 0988.[15] According to the FDA, Philips implemented "a preventative maintenance procedure for Trilogy devices, but Philips did not verify the effectiveness of this measure."[16]

61. The FDA pointed out that Philips' informal CAPA INV[17] related to these Trilogy devices did "not include, investigate, or examine all of your firm's CPAP and BiPAP medical devices, which also include similar air path assemblies and/or the affected polyester polyurethane foam, which is susceptible to degradation."[18] But Philips had acknowledged to the FDA that it had "received approximately eighty complaints related to foam degradation, **on non-Trilogy ventilator devices,** from 2014 to 2017."[19]

62. The FDA concluded that Philips had not "adequately established" procedures for initiating CAPA procedures.[20] Specifically, the FDA faulted Philips for not initiating a "formal" CAPA after receiving "various complaints alleging foam degradation in Trilogy ventilator devices" and then closing its informal investigation just two months later without "verify[ing] the effectiveness" of the limited "preventative maintenance procedure for Trilogy devices."[21]

63. Philips continued to receive more information that suggested that the PE-PUR Foam was prone to degradation. According to the FDA, "[a] follow-up email amongst your firm's [Philips'] personnel, dated 08/24/2018, states that testing confirmed that the affected foam breaks

---

[15] 483 Report at 15.
[16] 518(b) Notice at 8.
[17] The 483 Report explained that Philips's practice at the time was to first open CAPA requests- called "CAPA INVs"-as a precursor to a formal CAPA, but this could only occur if approved by a "CAPA Review Board" or delegate. *See* 483 Report at 14-15.
[18] *Id.* at 15.
[19] *Id.* at 16 (emphasis supplied).
[20] *Id.* at 15.
[21] 518(b) Notice at 8.

down in high heat and high humidity environments, which concurred with Trilogy ventilator related complaints . . . ."[22]

64. Nonetheless, Philips continued manufacturing and selling the Recalled Devices containing PE-PUR Foam and failed to warn users such as Sharon of the known risks of serious injury from continuing to use the subject device.

Philips Opened A Formal CAPA In 2019

65. In June 2019, Philips finally initiated a formal CAPA, numbered CAPA 7211, related to the issues associated with the PE-PUR Foam. But as the FDA explains:

> Even then, that CAPA failed to evaluate all relevant data. Philips' search of FDA's Manufacturer and User Facility Device Experience (MAUDE) database in connection with CAPA 7211 identified only three medical device reports (MDRs) associated with potential foam degradation involving Trilogy ventilators between January 2011 and January 2021. Yet an MOR analysis conducted by Philips in 2018 had already identified 17 documented complaints related to foam degradation in Trilogy ventilators, and at least 14 of those 17 complaints had related MDRs. Similarly, Philips' analysis of foam degradation-related complaints conducted in connection with CAPA 7211 identified 1,254 complaints confirmed to be related to foam degradation between 2014 and April 2021 across all affected products, yet this analysis failed to include several complaints confirmed to be related to foam degradation in Trilogy ventilators that were documented in 2018 in connection with **CAPA INV 0988.**[23]

66. Philips continued to test the PE-PUR Foam while the CAPA was underway. A Biological Risk Assessment dated July 2, 2020, found that "the biological and toxicological risks from exposure to degraded PE-PUR Foam are of concern. . . ."[24]

67. Another internal "Biological Risk Assessment" dated December 10, 2020 – and "conducted as a result of field reports/complaints regarding degraded sound abatement foam in

[22] 483 Report at 18.
[23] 518(b) Notice at 8-9.
[24] 483 Report at 7; *see also id.* ("Philips Respironics Inc. (PRI) was made aware in May 2019 that four CPAP units were returned to a service center with degraded sound abatement foam.")

various CPAP and ventilator products"[25] – described the risks that degraded polyurethane foam posed to humans in no uncertain terms:

> The cytotoxicity and positive genotoxicity results observed from degraded PE-PUR foam samples **indicate a potential patient risk. Potential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure.** Overall, based on an understanding of the toxicological significance of the foam degradants and the results of the ISO 10993 testing to include mutagenic responses in both a bacterial and mammalian system, **the degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to those patient populations who are exposed to degraded PE-PUR foam.**[26]

68. An additional Philips' Biocompatibility Risk Assessment dated January 11, 2021, concurred that degraded PE-PUR Foam "presents a significant biological risk to patients," and goes on to state that "[p]otential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure."[27]

69. Ultimately, in CAPA 7211, Philips concluded that "the cause of the foam degradation condition is long-term exposure to environmental conditions of high temperature combined with high humidity" and restated that "the cause of degradation was due to chemical breakdown of the foam due to exposure to water caused by long-term exposure to environmental conditions."[28]

70. Based on its investigation, the FDA concluded that Philips' upper management was aware of the foam degradation issues, discussed it at numerous management review meetings, and yet delayed doing anything about it – thereby knowingly placing users of its products such as Sharon at risk of serious injury or death:

> [F]irm management, including management with executive responsibility, were aware of potential foam degradation issues concerning CPAPs, BiPAPs, and Trilogy

---

[25] *Id.* at 8.
[26] *Id.* at 7-8 (emphasis added).
[27] *Id.* at 8.
[28] 518(b) Notice at 10.

> ventilators since at least 01/31/2020, or earlier, and implemented no further corrective actions until April 2021.
>
> Polyester polyurethane foam degradation issues concerning CPAPs, BiPAPs, and Trilogy Ventilators were discussed at all [redacted] management review meetings, since the 2019 [redacted], dated 01/31/2020 . . . . Additionally, your firm [Philips] became aware of this issue and related field complaints in at least 2015 or earlier.[29]

Until The Recall, Philips Advertised Its Breathing Machines As Safe And Effective

71. At no point prior to April 2021, when Philips first disclosed foam issues to its shareholders, did Philips even hint that there was a dangerous condition in the subject devices. Instead, Philips held itself out as a trusted brand and "global leader in the sleep and respiratory markets."[30] Philips further assures consumers like Sharon that its "sleep therapy systems are designed with the needs of care practitioners and patients in mind," and that its "quality systems reflect [Philips'] commitment to providing enhanced patient comfort," among other things. And it has long advertised its CPAP and BiPAP Machines as "clinically proven" treatment for sleep disorders.[31]

72. Philips boasts that it has the "most prescribed CPAP systems by U.S. sleep physicians."[32] The CPAP and BiPAP machines routinely cost from seven or eight hundred dollars to thousands of dollars per machine, and the ventilators cost more than several thousands of dollars per machine.

In April And May 2021, Philips Launched The DreamStation 2

73. Two months prior to the recall, Philips announced on April 13, 2021, that it was launching the DreamStation 2, a next-generation machine in its DreamStation product family. The DreamStation 2 does not contain PE-PUR Foam.

---

[29] 483 Report at 24.
[30] http://www.respironics.com/product library (last accessed June 16, 2022).
[31] https://www.usa.philips.com/healthcare/solutions/sleep (last accessed June 16, 2022).
[32] *See* https://www.usa.philips.com/healthcare/solutions/sleep/sleep-therapy (last accessed June 16, 2022) (citing 2016 Philips survey).

74. Less than two weeks after its launch of the DreamStation 2, on April 26, 2021, Philips finally announced what it had known for years – that its previous generation DreamStation products including the subject device posed serious health risks to users.[33]

75. Even then, Philips' April 26, 2021 statement to investors did not disclose the full extent of its knowledge about the risks posed by the PE-PUR Foam and attempted to deflect the blame on factors such as ozone cleaners. The FDA later rejected this notion, concluding that "the unreasonable risk associated with the products was not caused by the use of ozone cleaning agents, nor did the use of ozone to clean the products constitute a failure to exercise due care."[34]

76. When Philips finally did issue a recall on June 14, 2021, Philips advised CPAP and BiPAP users such as Sharon to "[d]iscontinue use of [their] device." Unfortunately for Sharon, the catastrophic damage to her lungs was already done.

77. On June 14, 2021, as a result of extensive ongoing review following the announcement on April 26, 2021, Philips issued a recall notification for specific affected devices, including the subject device.[35]

78. In its recall notification, Philips identified examples of potential risks which include exposure to degraded PE-PUR Foam particles and exposure to chemical emissions from the PE-PUR Foam material.

79. Philips reported that, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be

[33] https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-first-guarter-results-2021.html (last accessed June 16, 2022).
[34] 518(b) Notice at 10 (emphasis in original).
[35] On July 22, 2021, the FDA upgraded Philips' recall to its most serious classification, Class I: "A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."

life-threatening or cause permanent impairment or require medical intervention to preclude permanent impairment.

80. According to Philips' recall notice, the PE-PUR Foam used in Recalled Devices puts Recalled Device users at risk of suffering from the following health harms: "Particulate exposure can cause headache, irritation [skin, eye and respiratory tract], inflammation, respiratory issues and possible toxic and carcinogenic effects[;]" whereas the "potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting and possible toxic and carcinogenic effects."

81. At all times material, all Defendants participated in and unreasonably and unjustly profited from the manufacture, distribution and sale of the Recalled Devices and unreasonably put users of the Recalled Devices at risk of developing adverse health effects, including cancer.

The Plaintiffs

82. Sharon brings this action on behalf of herself as a purchaser and user of a recalled Philips' DreamStation Auto Continuous Positive Airway Pressure mechanical ventilator device. As a result of her usage of the subject device for three years, on or about August 11, 2022, Sharon was diagnosed with lung cancer, resulting in the need for a lobectomy.

83. Sharon's husband, Allen, brings a derivative claim for loss of consortium arising from injuries relating to those sustained by his lawful spouse, Sharon Lis.

84. At all times when Sharon used the subject device, she did so in accordance with the guidelines, manual, and instructions for use set forth by Defendants.

85. At all times when Sharon used the subject device, she did so for a purpose for which the subject device was marketed, designed, and intended by Defendants.

86. At all times when Sharon used the subject device, she did so in accordance with the directions and instructions issued by her physician who prescribed the use of the subject device.

87. After and as a result of using the subject device, Sharon has suffered personal injuries including but not limited to lung cancer. These injuries would not have occurred but for the defective nature of the subject device and Defendants' wrongful conduct alleged herein.

88. Sharon's use of the subject device caused, or significantly contributed to, her development and progression of lung cancer, which has permanently and irreparably injured her and damaged her quality of life.

89. By reason of the foregoing, Sharon has had to undergo significant treatment and will be required to undergo significant treatment in the future due to the defective nature of the subject device and/or Defendants' wrongful conduct.

90. As a result of the aforesaid conduct and subject device developed, manufactured, designed, sold, distributed, advertised, and promoted by Defendants, Plaintiff was seriously harmed and injured. As a result of such injuries, Plaintiff has suffered damages for which compensatory damages should be awarded.

91. The running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment and/or omission of critical safety information. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff and her physician, the true risks associated with the subject device created, designed, assembled, manufactured, constructed, produced, tested, packaged, labeled, marketed, advertised, promoted, made, distributed and/or sold by Defendants. Due to Defendants' actions, Plaintiff was unaware and could not have reasonably known, or learned through reasonable diligence, that she had been exposed to the risks and harms set forth and that those risks and harms were the direct and proximate result of Defendants' acts or omissions.

ARTICLE 16 ALLEGATIONS

92. If it is deemed that Article 16 of the CPLR applies to this action, the Plaintiffs assert that this action falls within one or more of the exceptions set forth in CPLR 1602 including, but not limited to, the exception for cases where a person is held liable for causing the claimant's injury by having acted with reckless disregard for the safety of others (CPLR 1602(7)); the exception for any parties found to have acted knowingly or intentionally and in concert to cause the acts or failures upon which liability is based (CPLR 1602(11)); and the exception for persons held liable in a product liability action where the manufacturer of the product is not a party to the action and jurisdiction over the manufacturer could not with due diligence be obtained (CPLR 1602(10)).

AS AND FOR A FIRST CAUSE OF ACTION IN NEGLIGENCE AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

93. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "92" of the Complaint herein with the same force and effect as if fully set forth herein.

94. Defendants had a duty to exercise reasonable care in designing, developing, researching, testing, manufacturing, marketing, supplying, promoting, selling and distributing the subject device.

95. Defendants knew, or should have known, that using the recalled devices, including the subject device, created a significantly increased risk of cancer, among other health harms.

96. Upon information and belief, the negligence of the Defendants, their agents, servants and/or employees, included but was not limited to the following acts and/or omissions: Defendants designed and developed the recalled devices, including the subject device, without thoroughly or adequately testing the devices; Defendants sold the recalled devices, including the subject device, without making proper and sufficient tests to determine the dangers to the users;

Defendants failed to adequately and correctly warn the Plaintiff, the public and the medical community of the cancer risks associated with the recalled devices, including the subject device; Defendants had a continuing duty to warn Plaintiff post-manufacture and sale of the dangers in its subject device; Defendants advertised and recommended the use of the recalled devices, including the subject device, for treatment of sleep apnea and other conditions without sufficient knowledge as to the significance of cancer risks; Defendants failed to exercise reasonable care in designing the recalled devices, including the subject device, in a manner which was dangerous to the users; Defendants negligently manufactured the recalled devices, including the subject device, in a manner which was dangerous to the users; Defendants failed to exercise reasonable care when they collectively decided to conceal information concerning cancer risks.

97. Upon information and belief, additionally, Defendants under-reported, underestimated and downplayed the serious dangers of the recalled devices, including the subject device's association with cancer and other health harms.

98. Upon information and belief, Defendants negligently compared the safety risk and/or dangers of the recalled devices, including the subject device, with other forms of treatment for sleep apnea and similar conditions.

99. Upon information and belief, Defendants also failed to warn Plaintiff and Plaintiff's physician, prior to actively encouraging the sale of the subject device, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early detection of cancer.

100. Upon information and belief, Defendants specifically failed to exercise reasonable care when they failed to accompany the subject device with proper and/or accurate warnings regarding all adverse side effects—namely cancer—associated with the use of the subject device. Once Defendants gained additional information about the Recalled Devices' association with

cancer, they failed to update their warnings and thereafter accompany the Recalled Devices with adequate warnings regarding cancer.

101. Upon information and belief, despite the fact that Defendants knew, or should have known, that the Recalled Devices caused unreasonably dangerous side effects, like cancer, they made conscious decisions to downplay these risks and continue to market, manufacture, distribute and/or sell the devices to physicians and patients, including Plaintiff Sharon Lis.

102. Upon information and belief, Defendants knew, or should have known, that consumers, such as Plaintiff Sharon Lis, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

103. Upon information and belief, Defendants' negligence was the proximate cause of Plaintiff Sharon Lis' injuries, among many other health harms, which Sharon Lis suffered and/or will continue to suffer.

104. As a result of the foregoing acts and omissions, Plaintiff Sharon Lis was caused to suffer serious and dangerous side effects that led to serious and permanent personal injuries, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications and fear of redeveloping cancer.

105. As a direct and proximate result of the Defendants' negligence, Plaintiff Sharon Lis suffered and will continue to suffer damages for which she is entitled to recovery.

106. Upon further information and belief, Defendants' conduct described herein consisted of misrepresentation, oppression, fraud and/or malice and was done with advance knowledge, conscious disregard of the safety of others and/or ratification by Defendants' officers, directors and/or managing agents.

107. Upon information and belief, despite their knowledge of the Recalled Devices' propensity to cause cancer and other serious injuries, Defendants chose profits over the safety of American citizens suffering with sleep apnea when they sought to create and market a device posing significant health risks.

108. Upon information and belief, despite having substantial information about the Recalled Devices' serious and unreasonable side effects, Defendants intentionally and recklessly failed to adequately warn the public, physicians and the medical community.

109. Upon information and belief, despite having substantial information about the Recalled Devices' serious and unreasonable side effects, Defendants failed to make the decision to pull the devices from the market after receiving indications and after receiving reports from consumers who were experiencing serious injuries associated with the use of the devices.

110. Upon information and belief, Defendants downplayed and recklessly disregarded their knowledge of the defective nature of the Recalled Devices' potential for causing serious injuries.

111. Upon information and belief, Defendants chose to do nothing to warn the public about the serious and undisclosed side effects with the Recalled Devices.

112. Upon information and belief, Defendants recklessly failed to warn and adequately instruct physicians, including Plaintiff Sharon Lis' physician, regarding the increase in reports from consumers who were experiencing serious injuries associated with the use of the Recalled Devices.

113. As a result of the negligence of the Defendants, the Plaintiff has been injured and is claiming damages in an amount exceeding the jurisdictional limits of all other courts which would otherwise have jurisdiction over this matter.

114. The intentional and willful conduct above complained of against the Defendants was aimed against the public as well as the Plaintiff; was grossly unjust and involved high moral culpability for which punitive damages should be assessed in a sum of money to be determined by the trier of fact.

AS AND FOR A SECOND CAUSE OF ACTION IN STRICT PRODUCTS LIABILITY – DESIGN DEFECT, AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

115. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "114" of the Complaint herein with the same force and effect as if fully set forth herein.

116. Upon information and belief, at all times herein mentioned, Defendants were involved in the business of researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices, including the subject device, which are defective and unreasonably dangerous.

117. Upon information and belief, the subject device was originally designed, sold and distributed by Defendants.

118. Upon information and belief, the design of the Recalled Device (including the subject device) and use of the PE-PUR Foam and the placement of the foam within the Recalled Devices, were defective and unreasonably dangerous, causing degradation and inhalation of the PE-PUR Foam and causing headaches, irritation, inflammation, respiratory issues and exposure to materials with toxic and carcinogenic effects.

119. Upon information and belief, the design of the Recalled Devices, including the subject device, and the PE-PUR Foam rendered devices, were not reasonably fit, suitable or safe for their intended purpose.

120. Upon information and belief, the Recalled Devices, including the subject device, did not perform as an ordinary consumer would expect.

121. Upon information and belief, at the time the Recalled Devices, including the subject device, were designed, manufactured, sold and distributed by Defendants, they were defective in design and unreasonably dangerous as designed.

122. Upon information and belief, at the time the subject device was sold, the defective design caused the product to unexpectedly fail to function in a manner reasonably expected by an ordinary consumer and user of such device. The defective and unreasonably dangerous design of the device was a proximate cause of the injuries and damages to the Plaintiff.

123. Upon information and belief, the dangers of the Recalled Devices, including the subject device, outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are other CPAP machines that do not use a similarly toxic foam that is subject to degradation, inhalation and ingestion.

124. Upon information and belief, safer alternative machines from other manufacturers were available that did not suffer from the defect as set forth herein and that did not have an unreasonable risk of harm as with the Recalled Devices, including the subject device, and their unsafe PE-PUR Foam.

125. Upon information and belief, the risk benefit profile of the Recalled Devices, including the subject device, was unreasonable and the Recalled Devices, including the subject device, should have had stronger and clearer warnings or should not have been sold in the market.

126. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable diligence, the defective nature of the subject device. Further, in no way could Plaintiff have known that Defendants had designed, developed, manufactured and distributed the subject device in a way as to make the risk of harm or injury outweigh any benefits.

127. The subject device was expected to and did reach Plaintiff Sharon Lis without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

128. At the time of the incident, the product was in substantially the same condition as it was at the time it was placed into the stream of commerce. No material alterations were made to the product. At the time of the incident, the product was in the same or substantially similar condition as when it left the control of Defendants.

129. The subject device was used for its intended purposes by Plaintiff Sharon Lis and the subject device was not materially altered or modified prior to its use.

130. Plaintiff Sharon Lis purchased the subject device on April 11, 2018.

131. Plaintiff Sharon Lis used the subject device regularly to treat a health condition until learning that the device was recalled on or about June 14, 2021.

132. Plaintiff Sharon Lis used the subject device in a foreseeable manner. Nonetheless, the use of the subject device was unreasonably dangerous and caused serious harm and injuries to Plaintiff.

133. The subject device was being used in a way which the Defendants intended at the time it was prescribed to Plaintiff Sharon Lis.

134. Defendants had a duty to create a device that was not unreasonably dangerous for its normal, intended use and breached this duty.

135. Upon information and belief, Defendants knew, or should have known, that the Recalled Devices, including the subject device, would be prescribed to patients and that physicians and patients were relying on them to furnish a suitable device. Further, Defendants knew, or should have known, that patients by whom the Recalled Devices would be used, such as Sharon Lis, could be and would be affected by the defective design and composition of the devices.

136. Upon information and belief, Defendants researched, designed, manufactured, tested, advertised, promoted, marketed and distributed a defective device which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiff Sharon Lis and her husband (loss of consortium), and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

137. As a direct and proximate result of Defendants' placement of the subject defective device into the stream of commerce and Plaintiff Sharon Lis' use of the product as designed, manufactured, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff Sharon Lis suffered serious physical and mental injuries including but not limited to lung cancer, debilitating injuries, harm, damages and economic loss and will continue to suffer great pain, discomfort, harm, damages and economic loss in the future as a result of being unable to attend to her ordinary affairs and she is and will remain disfigured.

138. That by reason of the foregoing, the Defendants are liable to Plaintiffs under New York's Strict Products Liability in the amount set forth in Paragraphs "113" and "114" of this Complaint.

139. That by reason of the foregoing on the part of the Defendants, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

AS AND FOR A THIRD CAUSE OF ACTION IN STRICT PRODUCTS LIABILITY – FAILURE TO WARN AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

140. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "139" of the Complaint herein with the same force and effect as if fully set forth herein.

141. Defendants had a duty to warn Plaintiff Sharon Lis regarding the defect and true risks associated with the Recalled Devices, including the subject device.

142. Upon information and belief, Defendants are liable under the theory of strict products liability. Defendants were, at all times relevant to this suit, engaged in the business of designing, manufacturing, testing, marketing, distributing and placing into the stream of commerce CPAP and BiPAP devices for sale to and for use by members of the public, including the subject device at issue in this lawsuit.

143. The subject device manufactured by Defendants reached Plaintiff Sharon Lis without substantial change and was used as directed. Upon information and belief, the subject device used by Plaintiff Sharon Lis was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Plaintiff Sharon Lis.

144. Defendants, as manufacturers of CPAP and BiPAP devices, are held to the level of knowledge of an expert in the field. Further, Defendants knew, or should have known, that warnings and other relevant information and data which they distributed regarding the defect of the device and associated health risks with the use of devices were inadequate.

145. Upon information and belief, at all times herein mentioned, Defendants designed, developed, researched, tested and knew, or should have known, about the significant cancer risks of the subject device.

146. At all times herein mentioned, Defendants advertised, promoted, marketed, sold and distributed the subject device that was used by Plaintiff Sharon Lis.

147. The subject device was expected to and did reach the usual consumers, handlers and persons coming into contact with said device without substantial change in the condition in which it was produced, manufactured, sold, distributed and marketed by the Defendants.

148. Defendants each had an independent duty and a continuing duty to warn the medical community and consumers, including Plaintiff Sharon Lis and her physician, about the significance of the risks of cancer and other health harms associated with the subject device as it became or could have become available to Defendants.

149. Plaintiff Sharon Lis used the subject device in a manner intended and foreseeable by Defendants.

150. Upon information and belief, the subject device was defective due to inadequate warnings because Defendants knew, or should have known, that the product created a significantly increased risk of cancer, among other health impacts, and failed to warn the medical community and Plaintiff's physician of the nature of such risks.

151. Defendants failed to provide adequate warnings regarding the risks of the PE-PUR Foam.

152. Upon information and belief, Defendants omitted and downplayed the significantly increased risks of cancer and other health risks associated with the Recalled Devices, including the subject device, that Defendants knew, or should have known, from previous testing and research even prior to subject device's FDA approval.

153. Upon information and belief, Defendants falsely represented to Plaintiff Sharon Lis and her physician that the subject device was safe for human use.

154. Upon information and belief, despite Defendants' obligation to unilaterally strengthen the warnings, Defendants instead chose to actively conceal this knowledge.

155. Upon information and belief, Defendants intentionally, knowingly and recklessly made these misrepresentations to induce Plaintiff's prescribing physician to prescribe and Plaintiff Sharon Lis to purchase, the Recalled subject device.

156. Plaintiff Sharon Lis and her prescribing physician did not have the same knowledge as Defendants and no adequate warning or other relevant information and data was communicated to Plaintiff Sharon Lis or her physician.

157. Among other defects, the subject device's labeling and warnings were defective because they omitted and inadequately warned of the device's risk of cancer and other health risks.

158. Upon information and belief, Defendants had information regarding the true risks but failed to warn Plaintiff Sharon Lis and her prescribing physician about the true risks stated herein and Defendants chose not to strengthen their warnings.

159. Although physicians are supposed to weigh the risks and benefits before prescribing a medical device, upon information and belief, Defendants knew that their deliberate omissions would cause physicians, including Plaintiff Sharon Lis' physician, to prescribe the subject device without being able to adequately weigh the risk of device's risk of cancer and other health risks.

160. If Defendants would have properly warned about the subject device's cancer risk and/or other health harms, Plaintiff Sharon Lis' prescribing physician would not have recommended or prescribed the subject device and Plaintiff Sharon Lis would not have purchased or used the subject device because the potential benefits of the subject device are significantly outweighed by the risk of cancer and other harms.

161. Had Defendants reasonably provided adequate warnings of cancer, such warnings would have been heeded and no healthcare professional, including Plaintiff Sharon Lis' physician, would have prescribed the subject device and no consumer, including Plaintiff Sharon Lis, would have purchased and/or used the subject device. Instead, Plaintiff's prescribing physician would have prescribed and Plaintiff Sharon Lis would have purchased and used a safer alternative device or recommended and used an alternative course of medical treatment that did not include the subject device.

162. Defendants had an obligation to provide Plaintiff Sharon Lis and Sharon Lis' physician with adequate information, data and warnings regarding the risks associated with the use of the subject device and/or that there existed safer and more or equally effective alternative devices.

163. Upon information and belief, Defendants knew that their representations to plaintiff about the Recalled Devices, including the subject device, were false in that the Recalled Devices, including the subject device, contained PE-PUR Foam that placed users like plaintiff at risk of adverse health effects from the continued inhalation of the Recalled Devices, including the subject device, which does not conform to the products' labels, packaging, advertising and statements.

164. Upon information and belief, Defendants knowingly allowed their packaging, labels, advertisements, promotional materials and websites to intentionally mislead consumers, such as Plaintiff Sharon Lis, and Plaintiff's prescribing physician.

165. Defendants marketed, promoted, distributed and sold the unreasonably dangerous and defective Recalled Devices, including the subject device, to consumers, Plaintiff Sharon Lis, and her prescribing physician without adequate warnings and other relevant information and data. Upon information and belief, through both omission and affirmative misstatements, Defendants misled Plaintiff Sharon Lis and her prescribing physician about the health risks associated with the use of the Recalled Devices, including the subject device, which resulted in injury to Plaintiff.

166. Plaintiff Sharon Lis would not have purchased, chosen, used and/or paid for all or part of the subject device and Plaintiff's prescribing physician would not have prescribed the subject device if they had known of the defect and the risks of purchasing and using the device.

167. Plaintiff Sharon Lis and Plaintiff's prescribing physician did in fact rely on these misrepresentations and omissions and Plaintiff Sharon Lis was prescribed and she purchased and used the subject device as a result of those misrepresentations and omissions. Given the deceptive

manner in which Defendants advertised, represented and otherwise promoted the Recalled Devices, including the subject device, Plaintiff's and Plaintiff's physician's reliance on Defendants' misrepresentations was justifiable.

168. By failing to provide Plaintiff Sharon Lis and her physician with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with use of the Recalled Devices, including the subject device, and/or that there existed safer and more equally effective alternative devices, Defendants breached their duty of reasonable care and safety.

169. Upon information and belief, Defendants' actions described above were performed willfully, intentionally and with reckless disregard of the life and safety of Plaintiff Sharon Lis and the public.

170. As a direct and proximate result of the subject device's defects as described herein that was placed into the stream of commerce, Plaintiff Sharon Lis developed cancer, suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has further suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost her ability to live a normal life and will continue to be so diminished in the future.

171. By reason of the foregoing, the Defendants are liable to the plaintiffs under New York Strict Products Liability in an amount set forth in Paragraphs "113" and "114" of this Complaint.

AS AND FOR A FOURTH CAUSE OF ACTION IN STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

172. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "171" of the Complaint herein with the same force and effect as if fully set forth herein.

173. Defendants are liable under the theory of strict products liability. Defendants were at all times relevant to this suit and are now engaged in the business of researching, designing, manufacturing, testing, marketing, selling, disturbing and/or placing into the stream of commerce the Recalled Devices, including the subject device, which are defective and unreasonably dangerous.

174. The subject device was expected to and did reach Plaintiff Sharon Lis without a substantial change in its condition.

175. Upon information and belief, the finished subject device deviated, in terms of construction and quality, from the specifications or planned output in a manner that made it unreasonably dangerous.

176. Upon information and belief, at all relevant times, the Recalled Devices, including the subject device, were defectively and improperly manufactured and designed by Defendants in that Defendants continued to supply consumers with the Recalled Devices despite having full knowledge that the devices posed substantial and avoidable bodily injury.

177. Upon information and belief, the foreseeable risks of the subject device were known to Defendants and could have been avoided.

178. Upon information and belief, at all relevant times, the subject device was defectively manufactured by Defendants in that its design and formulation is more dangerous than what an ordinary consumer would expect when used in an intended and reasonably foreseeable manner.

179. Upon information and belief, at all relevant times, Defendants actively deceived users that their use of the Recalled Devices posed safety risks that far outweighed any benefits.

180. Upon information and belief, the Recalled Devices, including the subject device, were defectively manufactured in that the PE-PUR Foam comprising part of the devices can

degrade into particles that enter the devices' air pathway and can off-gas certain chemicals. These characteristics cause, among other problems, cancer. Plaintiff Sharon Lis and other similarly situated consumers were unknowingly subjected to receiving different doses of toxins, carcinogens and other deleterious components and contaminants when using the Recalled Devices.

181. As a direct and proximate result of the defective manufacture of the subject device placed into the stream of commerce, Plaintiff Sharon Lis suffered and will continue to suffer damages for which she is entitled to recovery.

182. By reason of the foregoing, the Defendants are liable to the Plaintiff in an amount set forth in Paragraphs numbered "113" and "114" of this Complaint.

AS AND FOR A FIFTH CAUSE OF ACTION IN FRAUD AND MISREPRESENTATION AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

183. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "182" of the Complaint herein with the same force and effect as if fully set forth herein.

184. Upon information and belief, an inspection of Philips' internal company records conducted by the Food and Drug Administration (hereinafter "FDA") during August through November, 2021 reflects the following:

- As early as 2015, Philips was made aware that the polyester polyurethane foam in its devices was degrading during normal use;
- In 2016, Philips learned that the polyester polyurethane foam in its machines could degrade and break down in as little as one year of use;
- Records of users of Philips' devices reflect that since 2008, Philips received notice of over 222,000 complaints of degradation of the polyester polyurethane foam across all Philips' products containing the affected foam;

- By 2019, Philips was aware that biological risk assessments conducted in the field in response to reports/complaints regarding degraded and broken down polyester polyurethane foam in various CPAP products indicated the potential for cancer and other biological and toxicological risks from exposure to the degraded polyester polyurethane foam;
- As early as 2020, internal company documents revealed that the subject device failed emissions testing, exceeding tolerable limits, for the release of volatile organic compounds due to the foam's degrading.

185. As set forth above in Plaintiffs' "Factual Allegations", upon information and belief, Plaintiffs allege that Philips made affirmative misrepresentations regarding the safety and effectiveness of the subject device and omitted and withheld material safety information regarding the subject device to Plaintiff and her prescribing physician. Upon information and belief, among other wrongful conduct identified above, Philips fraudulently misrepresented the safety of its subject devices and failed to inform users and/or the medical profession that these devices containing polyester based polyurethane were breaking down into toxic particles that could be inhaled by users of these breathing machines.

186. Upon information and belief, plaintiff further alleges that during this period of time, while knowing that its polyester foam insulation devices were breaking down and releasing toxic particles that could be breathed in by the user, Philips failed to warn and continued to fraudulently misrepresent the safety of its products to users and the medical profession all to the detriment of plaintiff and others similarly situated.

187. Defendants had a duty to exercise reasonable care to those to whom they provided device information about the Recalled Devices and to all those relying on the information

provided, including Plaintiff Sharon Lis, her healthcare providers and the public in general that the devices had been tested and found to be safe and effective for treating sleep apnea.

188. Upon information and belief, Defendants, in the course of selling the Recalled Devices, supplied information about the devices through television commercials, advertisements, marketing campaigns, sales representatives, labeling and warnings.

189. Defendants breached their duty by misrepresenting the subject device's safety to the medical and healthcare community, to Plaintiff Sharon Lis and Plaintiff's prescribing physician.

190. Defendants failed to exercise reasonable care because their goal should have been to put safety before their profits by providing individuals with the realistic risks and expectations that the Recalled Devices could cause cancer and other serious injuries.

191. Defendants' representations were made without properly conducting sufficient testing and by providing insufficient warnings about the Recalled Devices' potential risks.

192. Defendants' false representations that the Recalled Devices were safe for consumers and their failure to disclose material past and existing facts of the Recalled Devices' risk of cancer were made or omitted with the intent to induce Plaintiff Sharon Lis and her prescribing physician to rely upon those facts or omissions.

193. Plaintiff Sharon Lis and her physician were unaware and did not know that the subject device was unsafe for the purpose of treating sleep apnea because it caused a significant increased risk of cancer until after she had been exposed to carcinogenic particles and gasses.

194. Plaintiff Sharon Lis and her physician justifiably relied upon the false representations and omissions of Defendants.

195. Had Defendants provided adequate warnings of cancer and other serious injuries, such warnings would have been heeded by plaintiff and her prescribing physician.

196. Had Defendants reasonably provided adequate warnings of cancer, such warnings would have been heeded and no healthcare professional, including Plaintiff Sharon Lis' physician, would have prescribed the subject device and no consumer, including Plaintiff Sharon Lis, would have purchased and/or used the subject device. Instead, Plaintiff's prescribing physician would have prescribed and Plaintiff Sharon Lis would have purchased and used a safer alternative device or recommended and used an alternative course of medical treatment that did not include the subject device.

197. As a direct and proximate result of the foregoing acts and omissions, Plaintiff Sharon Lis was caused to suffer serious and dangerous side effects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications and fear of redeveloping cancer and is entitled to an amount of damages as set forth in Paragraphs "113" and "114" of this Complaint. Plaintiffs do not allege a claim or cause of action for fraud on the FDA.

AS AND FOR A SIXTH CAUSE OF ACTION IN BREACH OF EXPRESS WARRANTY AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

198. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "197" of the Complaint herein with the same force and effect as if fully set forth herein.

199. At all relevant times, Defendants, through their advertising and promotional materials, expressly and impliedly warranted and affirmed that the subject devices' purpose was to offer a reasonably safe treatment for sleep apnea and similar health problems.

200. Upon information and belief, Defendants touted the subject devices as safe, despite knowingly having never adequately researched or tested the devices to assess their safety before placing the devices on the market and promoting them to consumers.

201. Defendants intended to make Plaintiff Sharon Lis and the general public believe the subject devices were safe.

202. Upon information and belief, Defendants knowingly mislead Plaintiff Sharon Lis and the general public to believe the subject devices were safe for use, despite knowing that the devices could lead to serious injuries, all of which Defendants knew, or by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff Sharon Lis would be victim to.

203. Upon information and belief, at all relevant times, Defendants had knowledge of the hazards and health risks posed by the Recalled Devices when used.

204. Upon information and belief, at all relevant times, Defendants willfully failed to disclose the defects and health risks of the Recalled Devices to Plaintiff Sharon Lis and the consuming public.

205. Plaintiff Sharon Lis relied, to her detriment, on the information publicized by Defendants.

206. In reliance upon these warranties as to the safety of the subject device by Defendants, Plaintiff Sharon Lis acquired/purchased and used the subject device, believing that the subject device was inherently safe.

207. Plaintiff Sharon Lis notified Defendants of the breach.

208. As a direct and proximate result of the foregoing acts and omissions, Plaintiff Sharon Lis suffered and will continue to suffer damages in an amount as set forth in Paragraphs "113" and "114" for which she is entitled to recovery.

AS AND FOR A SEVENTH CAUSE OF ACTION UNDER IMPLIED WARRANTY OF MERCHANTABILITY AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

209. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "208" of the Complaint herein with the same force and effect as if fully set forth herein.

210. Upon information and belief, at all relevant times, Defendants have been merchants in regard to the recalled devices, including the subject device, they created and sold to consumers.

211. Upon information and belief, Defendants breached their implied warranty of merchantability since the subject devices were defective when created and designed and do not conform with the promises represented on their labels.

212. Upon information and belief, Defendants failed to comply with merchantability requirements, as the subject devices do not achieve the ordinary purposes they advertise: a healthy treatment for respiratory conditions such as sleep apnea.

213. Beyond Defendants' own direct sales of the subject devices, Plaintiff Sharon Lis and other consumers are third-party beneficiaries of Defendants' agreements with their distributors, dealers and sellers for the distribution, dealing and sale of the Recalled Devices to consumers. Plaintiff Sharon Lis and consumers are the intended beneficiaries of Defendants' implied warranties since the Recalled Devices are manufactured with the express and intended purpose of selling the devices to consumers.

214. As a direct and proximate result of Defendants' breach of their implied warranties of merchantability regarding the subject device, Plaintiff Sharon Lis was damaged because, had she been aware of the unmerchantable condition of the subject device, she would have not acquired/purchased/used the subject device and not suffered injuries and damages from its use.

215. As a direct and proximate result of the foregoing acts and omissions, Plaintiff Sharon Lis suffered and will continue to suffer damages in an amount as set forth in Paragraphs "113" and "114" for which she is entitled to recovery.

AS AND FOR AN EIGHTH CAUSE OF ACTION UNDER LOSS OF CONSORTIUM AGAINST THE NAMED DEFENDANTS, PLAINTIFF ALLEN LIS ALLEGES:

216. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "215" of the Complaint herein with the same force and effect as if fully set forth herein.

217. At all relevant times, Plaintiff Allen Lis was and still is the lawful spouse of Plaintiff Sharon Lis and as such was entitled to her services.

218. At all relevant times, Plaintiff Allen Lis has been deprived of the services, society, companionship, consortium and support of his wife, Plaintiff Sharon Lis, all to his damage.

219. That by reason of the foregoing, Plaintiff Sharon Lis was compelled to seek and obtain medical aid and attention and Plaintiff Allen Lis did necessarily pay and become liable therefor, for medicines and medical care and upon information and belief, Plaintiff Sharon Lis will necessarily incur further similar expenses.

220. That by reason of the foregoing, Plaintiff Allen Lis has been damaged in an amount that exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

WHEREFORE, Plaintiffs demand judgment against the Defendants in the First, Second, Third, Fourth, Fifth, Sixth, Seventh and Eighth Causes of Action in an amount exceeding the jurisdictional limits of all other courts which would otherwise have jurisdiction over this matter; punitive damages in a sum of money to be determined by the trier of fact; and for such other and further relief as may be just and proper, together with the costs and disbursements of this action.

DEMAND FOR JURY TRIAL

221. Plaintiffs demand a jury trial on all counts in this Verified Complaint.

Dated this 10th day of August, 2023.

Michael A. Ponterio, Esq.
Lipsitz, Ponterio & Comerford LLC
424 Main Street, Suite 1500
Buffalo, NY 14202
Phone: (716) 849-0701
Fax: (716) 849-0708

Connor G. Sheehan, Esq.*
Texas Bar No. 24046827
csheehan@dunnsheehan.com
DUNN SHEEHAN LLP
5910 N. Central Expressway, Suite 1310
Dallas, Texas 75206
Phone: (214) 866-0077
Fax: (214) 866-0070
**pro hac vice application forthcoming*

Attorneys for Plaintiffs

VERIFICATION

STATE OF NEW YORK)
COUNTY OF ERIE) SS.:
CITY OF BUFFALO)

The undersigned, an attorney admitted to practice in the courts of the State of New York, shows: that deponent is a member of the firm of LIPSITZ, PONTERIO & COMERFORD LLC, the attorneys of record for the plaintiffs in the within action; that deponent has read the foregoing Verified Complaint and knows the contents thereof; that the same is true to deponent's own knowledge, except as to those matters therein stated to be alleged upon information and belief and as to those matters deponent believes it to be true. Deponent further says that the reason this verification is made by deponent and not by plaintiffs, SHARON LIS and ALLEN LIS, is because said plaintiffs are not in Erie County which is the county where deponent has his principal office.

The grounds of deponent's belief as to all matters not stated upon deponent's knowledge are as follows: records, reports and correspondence in deponent's file.

The undersigned affirms that the foregoing statements are true, under the penalties of perjury.

Dated: August 10, 2023

MICHAEL A. PONTERIO, ESQ.

EXHIBIT B

Notice of Service of Process

null / ALL
Transmittal Number: 27487574
Date Processed: 08/17/2023

Primary Contact:
Barbara Bickford
Philips North America LLC
222 Jacobs St
Fl 3
Cambridge, MA 02141-2289

Entity:	Philips North America LLC Entity ID Number 1920741
Entity Served:	Philips North America LLC
Title of Action:	Sharon Lis vs. Koninklijke Philips N.V.
Matter Name/ID:	Sharon Lis vs. Koninklijke Philips N.V. (14485630)
Document(s) Type:	Summons/Complaint
Nature of Action:	Product Liability
Court/Agency:	Niagara County Supreme Court, NY
Case/Reference No:	E180656/2023
Jurisdiction Served:	Delaware
Date Served on CSC:	08/17/2023
Answer or Appearance Due:	30 Days
Originally Served On:	CSC
How Served:	Personal Service
Sender Information:	Lipsitz, Ponterio & Comerford LLC 716-849-0701

Information contained on this transmittal form is for record keeping, notification and forwarding the attached document(s). It does not constitute a legal opinion. The recipient is responsible for interpreting the documents and taking appropriate action.

To avoid potential delay, please do not send your response to CSC

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NIAGARA

----------x

SHARON LIS and
ALLEN LIS, her spouse

Plaintiff/Petitioner,

- against -

Index No. E180656/2023

KONINKLIJKE PHILIPS N.V., et al.

Defendant/Respondent.

----------x

NOTICE OF ELECTRONIC FILING
(Consensual Case)
(Uniform Rule § 202.5-b)

You have received this Notice because:

1) The Plaintiff/Petitioner, whose name is listed above, has filed this case using the New York State Courts E-filing system ("NYSCEF"), and

2) You are a Defendant/Respondent (a party) in this case.

- **If you are represented by an attorney:**
  Give this Notice to your attorney. (Attorneys: see "Information for Attorneys" pg. 2).

- **If you are not represented by an attorney:**
  You will be served with all documents in paper and you must serve and file your documents in paper, unless you choose to participate in e-filing.

  If you choose to participate in e-filing, you must have access to a computer and a scanner or other device to convert documents into electronic format, a connection to the internet, and an e-mail address to receive service of documents.

  The **benefits of participating in e-filing** include:

  - serving and filing your documents electronically
  - free access to view and print your e-filed documents
  - limiting your number of trips to the courthouse
  - paying any court fees on-line (credit card needed)

  To register for e-filing or for more information about how e-filing works:

  - visit: www.nycourts.gov/efile-unrepresented or
  - contact the Clerk's Office or Help Center at the court where the case was filed. Court contact information can be found at www.nycourts.gov

To find legal information to help you represent yourself visit www.nycourthelp.gov

Information for Attorneys

An attorney representing a party who is served with this notice must either consent or decline consent to electronic filing and service through NYSCEF for this case.

Attorneys registered with NYSCEF may record their consent electronically in the manner provided at the NYSCEF site. Attorneys not registered with NYSCEF but intending to participate in e-filing must first create a NYSCEF account and obtain a user ID and password prior to recording their consent by going to www.nycourts.gov/efile

Attorneys declining to consent must file with the court and serve on all parties of record a declination of consent.

For additional information about electronic filing and to create a NYSCEF account, visit the NYSCEF website at www.nycourts.gov/efile or contact the NYSCEF Resource Center (phone: 646-386-3033; e-mail: nyscef@nycourts.gov).

Dated: August 10, 2023

Michael A. Ponterio, Esq.
Name

LIPSITZ, PONTERIO & COMERFORD, LLC
Firm Name

424 Main Street, Suite 1500

Buffalo, New York 14202
Address

(716) 849-0701
Phone

map@lipsitzponterio.com
E-Mail

TO: ALL NAMED DEFENDANTS

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NIAGARA

SHARON LIS and
ALLEN LIS, her spouse
5384 County Road 36
Honeoye, NY 14471

Plaintiffs,

vs.

KONINKLIJKE PHILIPS N.V.
Philips Center
Amstelplein 2,
1096 BC Amsterdam
The Netherlands

PHILIPS NORTH AMERICA LLC
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

PHILIPS RS NORTH AMERICA LLC
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

PHILIPS HOLDING USA, INC.
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

PHILIPS HEALTHCARE
222 Jacobs Street
Cambridge, MA 02141

HEALTH SYSTEM SERVICES, LTD.
6867 Williams Road
Niagara Falls, NY 14304

Defendants.

SUMMONS

Plaintiffs designate Niagara County as the place of trial

The basis of venue is the residence of a defendant

Defendant, Health System Services, Ltd., resides at 6867 Williams Road Niagara Falls, NY

County of Niagara

TO THE ABOVE-NAMED DEFENDANTS:

YOU ARE HEREBY SUMMONED to answer the Verified Complaint in this action and to serve a copy of your answer, or, if the Verified Complaint is not served with this Summons, to

serve a notice of appearance on the Plaintiffs' Attorneys within 20 days after the service of this Summons, exclusive of the day of service (or within 30 days after the service is complete if this Summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the Verified Complaint.

Dated: Buffalo, New York
August 10, 2023

Michael A. Ponterio, Esq.
Lipsitz, Ponterio & Comerford, LLC
424 Main Street, Suite 1500
Buffalo, NY 14202
Phone: 716.849.0701
Fax: 716.849.0708

Connor G. Sheehan*
Texas Bar No. 24046827
csheehan@dunnsheehan.com
DUNN SHEEHAN LLP
5910 N. Central Expressway, Suite 1310
Dallas, Texas 75206
Phone: 214.866.0077
Fax: 214.866.0070
**pro hac vice application forthcoming*

Attorneys for Plaintiffs

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NIAGARA

SHARON LIS and
ALLEN LIS, her spouse,

Plaintiffs,

VERIFIED COMPLAINT

vs.

KONINKLIJKE PHILIPS N.V.,
PHILIPS NORTH AMERICA LLC,
PHILIPS RS NORTH AMERICA LLC,
PHILIPS HOLDING USA, INC.,
PHILIPS HEALTHCARE,
HEALTH SYSTEM SERVICES, LTD.,

Defendants.

Plaintiffs SHARON LIS and ALLEN LIS ("Plaintiffs"), by and through their counsel, file this Verified Complaint against Defendants KONINKLIJKE PHILIPS N.V. ("Royal Philips"), PHILIPS NORTH AMERICA LLC ("Philips NA"), PHILIPS RS NORTH AMERICA LLC ("Philips RS"), PHILIPS HOLDING USA, Inc. ("PHUSA"), PHILIPS HEALTHCARE ("PHC" and, collectively with Royal Philips, Philips NA, Philips RS, and PHUSA, "Philips"), and HEALTH SYSTEM SERVICES, LTD. ("HSS" and, collectively with Philips, "Defendants").

INTRODUCTION

1. Plaintiff Sharon Lis ("Sharon") brings this action on behalf of herself for personal injuries that she sustained as a purchaser and long-time user of a defective Philips DreamStation Auto Continuous Positive Airway Pressure mechanical ventilator device (the "DreamStation CPAP machine" or "subject device") that contains polyester-based polyurethane sound abatement foam ("PE-PUR Foam"). On June 14, 2021, Phillips recalled the DreamStation CPAP machine due to the PE-PUR Foam's known propensity to break down, resulting in small pieces of foam and invisible chemicals being breathed in or swallowed by the user resulting in serious and permanent

injuries. Plaintiff Allen Lis ("Allen") brings a derivative claim for loss of consortium arising from injuries relating to those sustained by his lawful spouse, Sharon.

2. Philips develops, manufactures, markets, imports, sells, and distributes a variety of products for sleep and home respiratory care. Philips also develops, manufactures, markets, imports, sells, and distributes a variety of ventilator devices for patients with respiratory conditions.

3. On April 26, 2021, Philips publicly announced its determination that there were risks that the PE-PUR Foam used in certain CPAP, Bi-Level PAP, and mechanical ventilator devices manufactured by Philips – specifically including the subject device used by Sharon – will degrade or off-gas under certain circumstances.

4. On June 14, 2021, Royal Philips issued a recall ("Recall Notice") in the United States of its CPAP, Bi-Level PAP, and mechanical ventilator devices containing PE-PUR Foam – specifically including the subject device. In particular, Philips disclosed for the first time its determination that (a) the PE-PUR Foam in those devices emits volatile organic compounds which, when inhaled, can result in serious adverse health effects, including but not limited to acute respiratory distress syndrome (ARDS), lung disease, lung damage, chemical poisoning, heart attack, heart failure, kidney disease, reactive airway disease (RAD), respiratory failure, severe inflammation, and multiple types of cancer.

5. In total, Philips announced that "between 3 million and 4 million" devices were targeted in the recall. In its Recall Notice, Philips advised of serious health risks related to the PE-PUR Foam and recommended that patients using the recalled CPAP and Bi-Level PAP devices immediately discontinue use of the devices and consult with their physicians regarding alternative ventilator options.

6. On or about April 11, 2018 – more than three years before Philips issued the Recall Notice – the subject device used by Plaintiff Sharon Lis was distributed by HSS. This device, the Philips' subsequently-recalled devices, the DreamStation CPAP Machine, Serial No. J2125235256ED, was used by Plaintiff Sharon Lis to treat her obstructive sleep apnea. Sharon, a 55-year-old lifetime nonsmoker, used the CPAP device on a regular basis from the date she acquired it in early 2018 until approximately June 2021.

7. On or about August 11, 2022, as a result of her extended usage of the subject device, Sharon was diagnosed with bronchogenic carcinoma, a cancerous tumor originating in her lung along the right middle portion of her chest that can only be removed surgically. On or about November 2, 2022, Sharon underwent a right middle lobectomy to remove a section of the carcinoid tumor in her lung. The surgery resulted in only half of the cancerous tumor being removed due to its location on her lung.

8. As a direct and proximate result of her long-term use of Defendants' defective and dangerous device, Sharon has suffered and continues to suffer from severe symptoms of lung cancer, requiring continuous medical treatments and resulting in severe associated pain, suffering, and emotional distress.

9. Among other things, Sharon must have frequent scans of her body and blood work to determine if the cancer has grown or spread, which will result in a second surgery to remove the remainder of her cancerous lung. She is prescribed several pain medications to be able to tolerate the extreme pain that this cancer causes.

10. As a direct and proximate result of Defendants' wrongful conduct alleged herein, Sharon has suffered, continues to suffer, and will for the foreseeable future suffer from serious and dangerous side effects as a result of the cancer, as well as other severe and personal injuries which

are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and requires lifelong medical treatment and monitoring.

PARTIES

11. Plaintiffs are citizens of the State of New York, residing in Ontario County. Plaintiff Allen Lis is the lawful wedded spouse of Plaintiff Sharon Lis.

12. Upon information and belief, Defendant Royal Philips is a public limited liability company established under the laws of The Netherlands, having its principal executive offices at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the parent company of Philips North America, LLC and Philips RS North America, LLC.

13. Upon information and belief, Royal Philips controls Philips NA and Philips RS in the manufacturing, selling, distributing and supplying of the recalled CPAP, Bi-Level PAP and mechanical ventilator devices, including but not limited to the DreamStation CPAP Machine used by Plaintiff.

14. Upon information and belief, Defendant Philips NA is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly owned subsidiary of Royal Philips.

15. Upon information and belief, Defendant Philips RS is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS is a wholly owned subsidiary of Royal Philips. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.

16. Upon information and belief, Defendant PHUSA is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. PHUSA is a wholly owned subsidiary of Royal Philips.

17. Upon information and belief, Defendant Philips Healthcare is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Cambridge, Massachusetts 02141. That at all times hereinafter mentioned, it has been engaged in the sale, distribution and marketing of medical equipment including, but not limited to, the Philips DreamStation CPAP machine.

18. Upon information and belief, that at all times hereinafter mentioned, the Defendant, Health System Services, Ltd., was and still is a New York domestic business corporation duly organized under §402 of New York State Business Corporation Law. That at all times hereinafter mentioned, the Defendant, Health System Services, Ltd., has its principal place of business in Niagara Falls, New York. Venue is in Niagara County pursuant to CPLR 503 based upon Defendant, Health System Services, Ltd.'s principal place of business located at 6867 Williams Road, Niagara Falls, New York 14304, Niagara County.

JURISDICTION AND VENUE

19. Upon information and belief, at all relevant times, Defendant Royal Philips conducted business in the State of New York; transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; derived substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury to a person or property with the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

20. Upon information and belief, at all relevant times, Defendant Royal Philips shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times, Defendant Royal Philips was engaged in the business of designing, manufacturing, distributing, selling and marketing the subject device.

21. Upon information and belief, at all relevant times, Defendant Royal Philips NA transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; manufactured, distributed, designed and sold, the subject device with the serial number J2125235256ED.

22. Upon information and belief, at all relevant times, Defendant Philips NA is a Delaware corporation with its principal place of business located in Cambridge, Massachusetts. Defendant Philips NA is a wholly owned subsidiary of Defendant Royal Philips. Upon information and belief, Defendant Philips NA manages the operation of Defendant Royal Philips' various lines of business, including Philips RS. The sole member of Defendant Philips NA is Defendant PHUSA, which is a Delaware corporation with its principal place of business place of business in Cambridge, Massachusetts.

23. Upon information and belief, at all relevant times, Defendant Philips NA did business and contracted to supply goods or services in the State of New York; derived substantial profits from its sales in the State of New York; and committed a tortious act within the State of New York causing injury to a person or property within the State of New York.

24. Upon information and belief, at all relevant times, Defendant Philips NA was engaged in the business of designing, manufacturing, distributing, selling and marketing the subject device; shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce; transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302

25. Upon information and belief, at all relevant times, Defendant PHUSA is a Delaware corporation with its principal place of business in Cambridge, Massachusetts. Defendant PHUSA is a holding company that is the sole member of Defendant Philips NA.

26. Upon information and belief, at all relevant times, Defendant PHUSA shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times, Defendant PHUSA transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; derived substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury to a person or property with the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

27. Upon information and belief, at all relevant times, Defendant Philips RS is a Delaware corporation with its principal place of business in Pittsburgh, Pennsylvania. Defendant Philips RS was formerly operated under the business name Respironics, Inc. Defendant Royal Philips acquired Respironics, Inc. in 2008.

28. Upon information and belief, at all relevant times, Defendant Philips RS shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times, Defendant Philips RS was engaged in the business of designing, manufacturing, distributing, selling and marketing the subject device.

29. Upon information and belief, at all relevant times, Defendant Philips RS transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; did business in the State of New York; derived substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury

to a person or property within the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

30. Upon information and belief, at all relevant times, Defendant PHC is a Delaware company with its principal place of business in Cambridge, Massachusetts. At all relevant times, Defendant PHC was a foreign corporation, organized and existing pursuant to and by virtue of the laws of the State of Delaware that has authorization to do business in the State of New York.

31. Upon information and belief, at all relevant times, Defendant PHC shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times herein, Defendant PHC was engaged in the business of distributing, selling, promoting, advertising and marketing the subject device.

32. Upon information and belief, at all relevant times, Defendant PHC was and still is a corporation conducting business in the State of New York; Defendant PHC transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; derived substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury to a person or property within the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

33. Upon information and belief, Defendant HSS is a New York company with its principal place of business in Niagara Falls, New York. Defendant HSS distributed, shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times, Defendant HSS was engaged in the business of distributing, selling, promoting, advertising and marketing the subject device; was and still is a corporation conducting business in the State of New York; contracted to supply goods or services in the State of New York; derived

substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury to a person or property with the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

34. Upon information and belief, at all relevant times, Defendants (other than HSS) were the mere alter egos or instrumentalities of each other. There is such a unity of interest and ownership between Defendants that the separate personalities of their entities ceased to exist. Defendants (other than HSS) operated as a single enterprise, equally controlled each other's business affairs, commingled their assets and funds, disregarded corporate formalities and used each other as a corporate shield to defeat justice, perpetuate fraud and evade contractual and/or tort liability.

35. Upon information and belief, at all relevant times, Defendants acted in all respects as agents or apparent agents of one another. Upon information and belief, at all relevant times, Defendants acted in concert in the designing, manufacturing, marketing, promoting, advertising and selling of devices for the treatment of obstructive sleep apnea, including the subject device. Defendants combined their property and labor in a joint undertaking for profit, with rights of mutual control over each other, rendering them jointly liable to Plaintiffs.

36. Upon information and belief, Defendants' actions in marketing, distributing and selling their devices in New York should have led them to reasonably anticipate being brought into Court in New York.

37. Upon information and belief, Defendants have sufficient "minimum contacts" with New York that subjecting them to personal jurisdiction in New York does not offend traditional notions of fair play and substantial justice.

38. As detailed below, upon information and belief, Plaintiff Sharon Lis, age 55, suffered injuries from the subject device that Defendants negligently designed and/or

manufactured, sold and distributed. Thus, Defendants committed a tort in New York that caused injuries in New York and the Court has personal jurisdiction over Defendants under New York State's Long Arm Statute.

39. Upon information and belief, this Court has personal jurisdiction over Defendants Royal Philips, Philips NA, Philips RS, PHUSA, PHC and HSS because of their systematic and continuous contacts with New York as well as their maintenance of a registered agent for service of process in New York. Federal diversity jurisdiction does not exist because Defendant HSS is a resident and corporate citizen of New York with its headquarters located in Niagara County, New York.

40. This Court is a proper venue for this civil action because Defendant HSS has its principal place of business in Niagara County at 6867 Williams Road, Niagara Falls, New York and committed the tortious acts at issue in this Complaint in Niagara County, New York and other locations in New York. This Court's exercise of personal jurisdiction over Defendants comports with due process.

FACTUAL ALLEGATIONS

The Philips DreamStation CPAP Machine

41. Obstructive sleep apnea ("OSA") is a sleeping disorder in which breathing is disrupted temporarily during sleep periods when breathing stops or becomes very shallow. OSA is associated with fatigue, daytime sleepiness, interrupted sleep, or snoring, among other symptoms.

42. CPAP therapy helps treat sleep apnea by preventing the person's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

43. Bi-PAP therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air pressure in an individual's airway.

44. At all relevant times, Defendants developed, manufactured, marketed, sold, and distributed a lineup of CPAP and BiLevel PAP devices under the Philips "Sleep & Respiratory Care" portfolio. These devices are designed to assist individuals with a number of sleep, breathing and other respiratory conditions, including OSA.

45. Philips' flagship CPAP/BiPAP machine product family is known as the "DreamStation" family line, which includes the original DreamStation, launched in October 2015 and the DreamStation Go (a travel version). Phillips sold DreamStation products through its subsidiary Respironics, that Philips acquired in 2008.

46. Philips used PE-PUR Foam in the subject device even though it was widely known that this foam is susceptible to hydrolysis.[1] Philips brought the subject device to market through the FDA's 510(k) clearance process, which is less stringent than the FDA's Pre-Market Approval ("PMA") application process. Having placed the subject device on the market, Philips assumed various duties under federal and state law, including the duty to investigate complaints and injuries and report adverse events. Philips sold the subject device as a "clinically proven" treatment for sleep disorders, exposing users of the subject device such as Sharon at the known (to Defendants) and undisclosed risk of serious and debilitation injury. The subject device failed to comply with "current good manufacturing practice" requirements ("GMPs") and other obligations imposed by FDA regulations. For example, the PE-PUR Foam in the subject device degrades and exposes patients to toxic particles and VOCs, some of which are known or suspected carcinogens.

[1] Poly*ether* polyurethan foam, which is less prone to hydrolysis, was an available safer alternative.

47. Since 2008, Philips has received hundreds of thousands of complaints of foam degradation in the subject devices. Instead of acting, Philips turned a blind eye to the problem and actively concealed it.

Philips Knew Of The Dangers Of Pe-Pur Foam Since At Least 2015

48. In 2021, an FDA investigation concluded that Philips knew as early as 2015 – *i.e.*, three years before Sharon acquired the DreamStation CPAP machine that ultimately caused her cancer – that Defendants' CPAP machines were unsafe:

> Beginning in 2015, Philips received data from a variety of sources regarding degradation of the PE-PUR foam contained within the recalled devices, including complaints, test reports, information from suppliers, and information from another entity owned by Philips' parent company. Philips failed to adequately evaluate this data and incorporate it into its CAPA [Corrective and Preventive Actions] system for further investigation and potential mitigation, as required by current good manufacturing practice requirements codified in 21 C.F.R. § 820.100.[2]

49. The FDA's determination was based in part on twenty-one (21) site inspections of Philips' Murrysville, Pennsylvania facility between August 26, 2021, and November 9, 2021. The lead FDA investigator, Katelyn A. Staub-Zamperini, memorialized the agency's finding in a 28-page FDA, 483 Report issued on November 9, 2021.[3]

50. In connection with its investigation, the FDA learned that Philips had received numerous complaints from customers about degradation of the foam in its Recalled Devices from at least as early as 2008:

> [A] query of your firm's consumer complaints from 01/01/2008 to current, for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black, **resulted in over 222,000 complaints, and over 20,000 of which occurred between 2008 to 2017 and involved Trilogy devices.** Additionally, your firm performed a foam related complaint data analysis in April 2021 on complaints confirmed to be related to or involve foam degradation issues. The raw complaint data documents that **30 Trilogy related complaints were received from 2014 to**

[2] https://www.fda.gov/media/158129/download (last accessed June 16, 2022) ("518(b) Notice"), at 6.
[3] A 483 Report is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. A redacted version of the 483 report is available here: https://www.fda.gov/media/l 54244/download (last accessed June I6, 2022).

2017, and 1,254 related complaints were received across all products containing the affected foam, from 2014 to 2021.[4]

51. The FDA also concluded that "[n]o formal investigation, risk analysis, or CAPA[5] were initiated, performed, or documented [by or on behalf of Philips], in response to the at least 222,000 complaints that could potentially be related to foam degradation and received from 2008 to 2017."[6] Further, the FDA determined that Philips "was made aware of polyester polyurethane foam degradation issues in/around October 2015 . . ."[7]

52. The FDA also found that Philips' analysis of consumer complaints was defective in that it "was not adequately performed to identify or detect quality problems";[8] that "potential foam degradation in Trilogy ventilator devices is not an isolated incident, and you [Philips] also have not documented a detailed rationale for why harm is not likely to occur again, as required by your Health Hazard Evaluation's instructions";[9] and that Philips' "risk analysis is inadequate or was not performed when appropriate or within an appropriate time frame of your firm becoming aware" of these issues.[10]

53. On May 2, 2022, the FDA issued a formal notice to Philips pursuant to Section 518(b) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360h(b) (the "518(b) Notice").[11]

54. The 518(b) Notice stated that "there is sufficient evidence for FDA to determine that the devices subject to the recall present an unreasonable risk of substantial harm to the public health" and "that there are reasonable grounds to believe that the recalled devices that Philips

---

[4] 483 Report at 12 (emphasis added).
[5] A Corrective and Preventative Action ("CAPA") refers to procedures that medical device manufactures must follow to identify and attempt to correct when a quality problem is detected. *See* 21 C.F.R. § 820.100.
[6] *Id.* at 16.
[7] 483 Report at 18.
[8] 483 Report at 16.
[9] *Id.* at 13.
[10] *Id.* at 3.
[11] https://www.fda.gov/media/158129/download (last accessed June 16, 2022).

manufactured after November 2015 were not properly manufactured with reference to the state of the art as it existed at the time of the devices' manufacture."[12]

55. The FDA also concluded that "[t]his risk is not the unavoidable byproduct of current ventilator, CPAP machine, and BiPAP machine technologies. Indeed, Philips and its competitors market ventilators, CPAP machines, and BiPAP machines that do not use PE-PUR Foam."[13]

56. The FDA's findings are directly applicable to the Philips DreamStation CPAP machine that caused Sharon's lung cancer.

57. Knowing about these safety issues with the PE-PUR Foam, Philips tested the foam material used in its Recalled Devices. According to the FDA, "this testing spoke only to the limited finding that in the case of the [redacted] foam samples 'returned from service in a Pacific rim location,' spectroscopy results were 'consistent with an environmental/chemical exposure causing base polymer cleavage and embrittlement of the material."[14] Nonetheless, based on the results of this limited testing, Philips concluded that no escalation to a CAPA process was required.

58. Philips was alerted to more warning signs of the dangers of the subject device as it continued to ask its supplier about the properties of the PE-PUR Foam it was continuing to put in medical devices that millions of its customers, including Sharon, were breathing through nightly to help their sleeping disorders with no way to know that they were exposing themselves to deadly respiratory conditions and cancers.

Philips Opened An Internal Investigation Into Foam Degradation In Mid-2018

59. On April 12, 2018, almost to the day when Sharon acquired and began to use the subject device, Philips opened a precursor to a formal CAPA, referred to by Philips as a CAPA

[12] *Id.* at 2.
[13] *Id.* at 6
[14] 518(b) Notice at 7.

INV 0988, "to investigate complaints related to potential foam degradation for the Trilogy devices in Australia and to determine what actions should be taken."[50]

60. On June 20, 2018, Philips closed CAPA INV 0988.[15] According to the FDA, Philips implemented "a preventative maintenance procedure for Trilogy devices, but Philips did not verify the effectiveness of this measure."[16]

61. The FDA pointed out that Philips' informal CAPA INV[17] related to these Trilogy devices did "not include, investigate, or examine all of your firm's CPAP and BiPAP medical devices, which also include similar air path assemblies and/or the affected polyester polyurethane foam, which is susceptible to degradation."[18] But Philips had acknowledged to the FDA that it had "received approximately eighty complaints related to foam degradation, **on non-Trilogy ventilator devices,** from 2014 to 2017."[19]

62. The FDA concluded that Philips had not "adequately established" procedures for initiating CAPA procedures.[20] Specifically, the FDA faulted Philips for not initiating a "formal" CAPA after receiving "various complaints alleging foam degradation in Trilogy ventilator devices" and then closing its informal investigation just two months later without "verify[ing] the effectiveness" of the limited "preventative maintenance procedure for Trilogy devices."[21]

63. Philips continued to receive more information that suggested that the PE-PUR Foam was prone to degradation. According to the FDA, "[a] follow-up email amongst your firm's [Philips'] personnel, dated 08/24/2018, states that testing confirmed that the affected foam breaks

---

[15] 483 Report at 15.
[16] 518(b) Notice at 8.
[17] The 483 Report explained that Philips's practice at the time was to first open CAPA requests- called "CAPA INVs"-as a precursor to a formal CAPA, but this could only occur if approved by a "CAPA Review Board" or delegate. *See* 483 Report at 14-15.
[18] *Id.* at 15.
[19] *Id.* at 16 (emphasis supplied).
[20] *Id.* at 15.
[21] 518(b) Notice at 8.

down in high heat and high humidity environments, which concurred with Trilogy ventilator related complaints . . . ."[22]

64. Nonetheless, Philips continued manufacturing and selling the Recalled Devices containing PE-PUR Foam and failed to warn users such as Sharon of the known risks of serious injury from continuing to use the subject device.

Philips Opened A Formal CAPA In 2019

65. In June 2019, Philips finally initiated a formal CAPA, numbered CAPA 7211, related to the issues associated with the PE-PUR Foam. But as the FDA explains:

> Even then, that CAPA failed to evaluate all relevant data. Philips' search of FDA's Manufacturer and User Facility Device Experience (MAUDE) database in connection with CAPA 7211 identified only three medical device reports (MDRs) associated with potential foam degradation involving Trilogy ventilators between January 2011 and January 2021. Yet an MOR analysis conducted by Philips in 2018 had already identified 17 documented complaints related to foam degradation in Trilogy ventilators, and at least 14 of those 17 complaints had related MDRs. Similarly, Philips' analysis of foam degradation-related complaints conducted in connection with CAPA 7211 identified 1,254 complaints confirmed to be related to foam degradation between 2014 and April 2021 across all affected products, yet this analysis failed to include several complaints confirmed to be related to foam degradation in Trilogy ventilators that were documented in 2018 in connection with **CAPA INV 0988.**[23]

66. Philips continued to test the PE-PUR Foam while the CAPA was underway. A Biological Risk Assessment dated July 2, 2020, found that "the biological and toxicological risks from exposure to degraded PE-PUR Foam are of concern. . . ."[24]

67. Another internal "Biological Risk Assessment" dated December 10, 2020 – and "conducted as a result of field reports/complaints regarding degraded sound abatement foam in

[22] 483 Report at 18.
[23] 518(b) Notice at 8-9.
[24] 483 Report at 7; *see also id.* ("Philips Respironics Inc. (PRI) was made aware in May 2019 that four CPAP units were returned to a service center with degraded sound abatement foam.")

various CPAP and ventilator products"[25] – described the risks that degraded polyurethane foam posed to humans in no uncertain terms:

> The cytotoxicity and positive genotoxicity results observed from degraded PE-PUR foam samples **indicate a potential patient risk. Potential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure.** Overall, based on an understanding of the toxicological significance of the foam degradants and the results of the ISO 10993 testing to include mutagenic responses in both a bacterial and mammalian system, **the degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to those patient populations who are exposed to degraded PE-PUR foam.**[26]

68. An additional Philips' Biocompatibility Risk Assessment dated January 11, 2021, concurred that degraded PE-PUR Foam "presents a significant biological risk to patients," and goes on to state that "[p]otential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure."[27]

69. Ultimately, in CAPA 7211, Philips concluded that "the cause of the foam degradation condition is long-term exposure to environmental conditions of high temperature combined with high humidity" and restated that "the cause of degradation was due to chemical breakdown of the foam due to exposure to water caused by long-term exposure to environmental conditions."[28]

70. Based on its investigation, the FDA concluded that Philips' upper management was aware of the foam degradation issues, discussed it at numerous management review meetings, and yet delayed doing anything about it – thereby knowingly placing users of its products such as Sharon at risk of serious injury or death:

> [F]irm management, including management with executive responsibility, were aware of potential foam degradation issues concerning CPAPs, BiPAPs, and Trilogy

[25] *Id.* at 8.
[26] *Id.* at 7-8 (emphasis added).
[27] *Id.* at 8.
[28] 518(b) Notice at 10.

> ventilators since at least 01/31/2020, or earlier, and implemented no further corrective actions until April 2021.
>
> Polyester polyurethane foam degradation issues concerning CPAPs, BiPAPs, and Trilogy Ventilators were discussed at all [redacted] management review meetings, since the 2019 [redacted], dated 01/31/2020 . . . . Additionally, your firm [Philips] became aware of this issue and related field complaints in at least 2015 or earlier.[29]

Until The Recall, Philips Advertised Its Breathing Machines As Safe And Effective

71. At no point prior to April 2021, when Philips first disclosed foam issues to its shareholders, did Philips even hint that there was a dangerous condition in the subject devices. Instead, Philips held itself out as a trusted brand and "global leader in the sleep and respiratory markets."[30] Philips further assures consumers like Sharon that its "sleep therapy systems are designed with the needs of care practitioners and patients in mind," and that its "quality systems reflect [Philips'] commitment to providing enhanced patient comfort," among other things. And it has long advertised its CPAP and BiPAP Machines as "clinically proven" treatment for sleep disorders.[31]

72. Philips boasts that it has the "most prescribed CPAP systems by U.S. sleep physicians."[32] The CPAP and BiPAP machines routinely cost from seven or eight hundred dollars to thousands of dollars per machine, and the ventilators cost more than several thousands of dollars per machine.

In April And May 2021, Philips Launched The DreamStation 2

73. Two months prior to the recall, Philips announced on April 13, 2021, that it was launching the DreamStation 2, a next-generation machine in its DreamStation product family. The DreamStation 2 does not contain PE-PUR Foam.

---

[29] 483 Report at 24.
[30] http://www.respironics.com/product library (last accessed June 16, 2022).
[31] https://www.usa.philips.com/healthcare/solutions/sleep (last accessed June 16, 2022).
[32] *See* https://www.usa.philips.com/healthcare/solutions/sleep/sleep-therapy (last accessed June 16, 2022) (citing 2016 Philips survey).

74. Less than two weeks after its launch of the DreamStation 2, on April 26, 2021, Philips finally announced what it had known for years – that its previous generation DreamStation products including the subject device posed serious health risks to users.[33]

75. Even then, Philips' April 26, 2021 statement to investors did not disclose the full extent of its knowledge about the risks posed by the PE-PUR Foam and attempted to deflect the blame on factors such as ozone cleaners. The FDA later rejected this notion, concluding that "the unreasonable risk associated with the products was not caused by the use of ozone cleaning agents, nor did the use of ozone to clean the products constitute a failure to exercise due care."[34]

76. When Philips finally did issue a recall on June 14, 2021, Philips advised CPAP and BiPAP users such as Sharon to "[d]iscontinue use of [their] device." Unfortunately for Sharon, the catastrophic damage to her lungs was already done.

77. On June 14, 2021, as a result of extensive ongoing review following the announcement on April 26, 2021, Philips issued a recall notification for specific affected devices, including the subject device.[35]

78. In its recall notification, Philips identified examples of potential risks which include exposure to degraded PE-PUR Foam particles and exposure to chemical emissions from the PE-PUR Foam material.

79. Philips reported that, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be

[33] https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-first-guarter-results-2021.html (last accessed June 16, 2022).
[34] 518(b) Notice at 10 (emphasis in original).
[35] On July 22, 2021, the FDA upgraded Philips' recall to its most serious classification, Class I: "A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."

life-threatening or cause permanent impairment or require medical intervention to preclude permanent impairment.

80. According to Philips' recall notice, the PE-PUR Foam used in Recalled Devices puts Recalled Device users at risk of suffering from the following health harms: "Particulate exposure can cause headache, irritation [skin, eye and respiratory tract], inflammation, respiratory issues and possible toxic and carcinogenic effects[;]" whereas the "potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting and possible toxic and carcinogenic effects."

81. At all times material, all Defendants participated in and unreasonably and unjustly profited from the manufacture, distribution and sale of the Recalled Devices and unreasonably put users of the Recalled Devices at risk of developing adverse health effects, including cancer.

The Plaintiffs

82. Sharon brings this action on behalf of herself as a purchaser and user of a recalled Philips' DreamStation Auto Continuous Positive Airway Pressure mechanical ventilator device. As a result of her usage of the subject device for three years, on or about August 11, 2022, Sharon was diagnosed with lung cancer, resulting in the need for a lobectomy.

83. Sharon's husband, Allen, brings a derivative claim for loss of consortium arising from injuries relating to those sustained by his lawful spouse, Sharon Lis.

84. At all times when Sharon used the subject device, she did so in accordance with the guidelines, manual, and instructions for use set forth by Defendants.

85. At all times when Sharon used the subject device, she did so for a purpose for which the subject device was marketed, designed, and intended by Defendants.

86. At all times when Sharon used the subject device, she did so in accordance with the directions and instructions issued by her physician who prescribed the use of the subject device.

87. After and as a result of using the subject device, Sharon has suffered personal injuries including but not limited to lung cancer. These injuries would not have occurred but for the defective nature of the subject device and Defendants' wrongful conduct alleged herein.

88. Sharon's use of the subject device caused, or significantly contributed to, her development and progression of lung cancer, which has permanently and irreparably injured her and damaged her quality of life.

89. By reason of the foregoing, Sharon has had to undergo significant treatment and will be required to undergo significant treatment in the future due to the defective nature of the subject device and/or Defendants' wrongful conduct.

90. As a result of the aforesaid conduct and subject device developed, manufactured, designed, sold, distributed, advertised, and promoted by Defendants, Plaintiff was seriously harmed and injured. As a result of such injuries, Plaintiff has suffered damages for which compensatory damages should be awarded.

91. The running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment and/or omission of critical safety information. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff and her physician, the true risks associated with the subject device created, designed, assembled, manufactured, constructed, produced, tested, packaged, labeled, marketed, advertised, promoted, made, distributed and/or sold by Defendants. Due to Defendants' actions, Plaintiff was unaware and could not have reasonably known, or learned through reasonable diligence, that she had been exposed to the risks and harms set forth and that those risks and harms were the direct and proximate result of Defendants' acts or omissions.

ARTICLE 16 ALLEGATIONS

92. If it is deemed that Article 16 of the CPLR applies to this action, the Plaintiffs assert that this action falls within one or more of the exceptions set forth in CPLR 1602 including, but not limited to, the exception for cases where a person is held liable for causing the claimant's injury by having acted with reckless disregard for the safety of others (CPLR 1602(7)); the exception for any parties found to have acted knowingly or intentionally and in concert to cause the acts or failures upon which liability is based (CPLR 1602(11)); and the exception for persons held liable in a product liability action where the manufacturer of the product is not a party to the action and jurisdiction over the manufacturer could not with due diligence be obtained (CPLR 1602(10)).

AS AND FOR A FIRST CAUSE OF ACTION IN NEGLIGENCE AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

93. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "92" of the Complaint herein with the same force and effect as if fully set forth herein.

94. Defendants had a duty to exercise reasonable care in designing, developing, researching, testing, manufacturing, marketing, supplying, promoting, selling and distributing the subject device.

95. Defendants knew, or should have known, that using the recalled devices, including the subject device, created a significantly increased risk of cancer, among other health harms.

96. Upon information and belief, the negligence of the Defendants, their agents, servants and/or employees, included but was not limited to the following acts and/or omissions: Defendants designed and developed the recalled devices, including the subject device, without thoroughly or adequately testing the devices; Defendants sold the recalled devices, including the subject device, without making proper and sufficient tests to determine the dangers to the users;

Defendants failed to adequately and correctly warn the Plaintiff, the public and the medical community of the cancer risks associated with the recalled devices, including the subject device; Defendants had a continuing duty to warn Plaintiff post-manufacture and sale of the dangers in its subject device; Defendants advertised and recommended the use of the recalled devices, including the subject device, for treatment of sleep apnea and other conditions without sufficient knowledge as to the significance of cancer risks; Defendants failed to exercise reasonable care in designing the recalled devices, including the subject device, in a manner which was dangerous to the users; Defendants negligently manufactured the recalled devices, including the subject device, in a manner which was dangerous to the users; Defendants failed to exercise reasonable care when they collectively decided to conceal information concerning cancer risks.

97. Upon information and belief, additionally, Defendants under-reported, underestimated and downplayed the serious dangers of the recalled devices, including the subject device's association with cancer and other health harms.

98. Upon information and belief, Defendants negligently compared the safety risk and/or dangers of the recalled devices, including the subject device, with other forms of treatment for sleep apnea and similar conditions.

99. Upon information and belief, Defendants also failed to warn Plaintiff and Plaintiff's physician, prior to actively encouraging the sale of the subject device, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early detection of cancer.

100. Upon information and belief, Defendants specifically failed to exercise reasonable care when they failed to accompany the subject device with proper and/or accurate warnings regarding all adverse side effects—namely cancer—associated with the use of the subject device. Once Defendants gained additional information about the Recalled Devices' association with

cancer, they failed to update their warnings and thereafter accompany the Recalled Devices with adequate warnings regarding cancer.

101. Upon information and belief, despite the fact that Defendants knew, or should have known, that the Recalled Devices caused unreasonably dangerous side effects, like cancer, they made conscious decisions to downplay these risks and continue to market, manufacture, distribute and/or sell the devices to physicians and patients, including Plaintiff Sharon Lis.

102. Upon information and belief, Defendants knew, or should have known, that consumers, such as Plaintiff Sharon Lis, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

103. Upon information and belief, Defendants' negligence was the proximate cause of Plaintiff Sharon Lis' injuries, among many other health harms, which Sharon Lis suffered and/or will continue to suffer.

104. As a result of the foregoing acts and omissions, Plaintiff Sharon Lis was caused to suffer serious and dangerous side effects that led to serious and permanent personal injuries, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications and fear of redeveloping cancer.

105. As a direct and proximate result of the Defendants' negligence, Plaintiff Sharon Lis suffered and will continue to suffer damages for which she is entitled to recovery.

106. Upon further information and belief, Defendants' conduct described herein consisted of misrepresentation, oppression, fraud and/or malice and was done with advance knowledge, conscious disregard of the safety of others and/or ratification by Defendants' officers, directors and/or managing agents.

107. Upon information and belief, despite their knowledge of the Recalled Devices' propensity to cause cancer and other serious injuries, Defendants chose profits over the safety of American citizens suffering with sleep apnea when they sought to create and market a device posing significant health risks.

108. Upon information and belief, despite having substantial information about the Recalled Devices' serious and unreasonable side effects, Defendants intentionally and recklessly failed to adequately warn the public, physicians and the medical community.

109. Upon information and belief, despite having substantial information about the Recalled Devices' serious and unreasonable side effects, Defendants failed to make the decision to pull the devices from the market after receiving indications and after receiving reports from consumers who were experiencing serious injuries associated with the use of the devices.

110. Upon information and belief, Defendants downplayed and recklessly disregarded their knowledge of the defective nature of the Recalled Devices' potential for causing serious injuries.

111. Upon information and belief, Defendants chose to do nothing to warn the public about the serious and undisclosed side effects with the Recalled Devices.

112. Upon information and belief, Defendants recklessly failed to warn and adequately instruct physicians, including Plaintiff Sharon Lis' physician, regarding the increase in reports from consumers who were experiencing serious injuries associated with the use of the Recalled Devices.

113. As a result of the negligence of the Defendants, the Plaintiff has been injured and is claiming damages in an amount exceeding the jurisdictional limits of all other courts which would otherwise have jurisdiction over this matter.

114. The intentional and willful conduct above complained of against the Defendants was aimed against the public as well as the Plaintiff; was grossly unjust and involved high moral culpability for which punitive damages should be assessed in a sum of money to be determined by the trier of fact.

AS AND FOR A SECOND CAUSE OF ACTION IN STRICT PRODUCTS LIABILITY – DESIGN DEFECT, AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

115. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "114" of the Complaint herein with the same force and effect as if fully set forth herein.

116. Upon information and belief, at all times herein mentioned, Defendants were involved in the business of researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices, including the subject device, which are defective and unreasonably dangerous.

117. Upon information and belief, the subject device was originally designed, sold and distributed by Defendants.

118. Upon information and belief, the design of the Recalled Device (including the subject device) and use of the PE-PUR Foam and the placement of the foam within the Recalled Devices, were defective and unreasonably dangerous, causing degradation and inhalation of the PE-PUR Foam and causing headaches, irritation, inflammation, respiratory issues and exposure to materials with toxic and carcinogenic effects.

119. Upon information and belief, the design of the Recalled Devices, including the subject device, and the PE-PUR Foam rendered devices, were not reasonably fit, suitable or safe for their intended purpose.

120. Upon information and belief, the Recalled Devices, including the subject device, did not perform as an ordinary consumer would expect.

121. Upon information and belief, at the time the Recalled Devices, including the subject device, were designed, manufactured, sold and distributed by Defendants, they were defective in design and unreasonably dangerous as designed.

122. Upon information and belief, at the time the subject device was sold, the defective design caused the product to unexpectedly fail to function in a manner reasonably expected by an ordinary consumer and user of such device. The defective and unreasonably dangerous design of the device was a proximate cause of the injuries and damages to the Plaintiff.

123. Upon information and belief, the dangers of the Recalled Devices, including the subject device, outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are other CPAP machines that do not use a similarly toxic foam that is subject to degradation, inhalation and ingestion.

124. Upon information and belief, safer alternative machines from other manufacturers were available that did not suffer from the defect as set forth herein and that did not have an unreasonable risk of harm as with the Recalled Devices, including the subject device, and their unsafe PE-PUR Foam.

125. Upon information and belief, the risk benefit profile of the Recalled Devices, including the subject device, was unreasonable and the Recalled Devices, including the subject device, should have had stronger and clearer warnings or should not have been sold in the market.

126. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable diligence, the defective nature of the subject device. Further, in no way could Plaintiff have known that Defendants had designed, developed, manufactured and distributed the subject device in a way as to make the risk of harm or injury outweigh any benefits.

127. The subject device was expected to and did reach Plaintiff Sharon Lis without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

128. At the time of the incident, the product was in substantially the same condition as it was at the time it was placed into the stream of commerce. No material alterations were made to the product. At the time of the incident, the product was in the same or substantially similar condition as when it left the control of Defendants.

129. The subject device was used for its intended purposes by Plaintiff Sharon Lis and the subject device was not materially altered or modified prior to its use.

130. Plaintiff Sharon Lis purchased the subject device on April 11, 2018.

131. Plaintiff Sharon Lis used the subject device regularly to treat a health condition until learning that the device was recalled on or about June 14, 2021.

132. Plaintiff Sharon Lis used the subject device in a foreseeable manner. Nonetheless, the use of the subject device was unreasonably dangerous and caused serious harm and injuries to Plaintiff.

133. The subject device was being used in a way which the Defendants intended at the time it was prescribed to Plaintiff Sharon Lis.

134. Defendants had a duty to create a device that was not unreasonably dangerous for its normal, intended use and breached this duty.

135. Upon information and belief, Defendants knew, or should have known, that the Recalled Devices, including the subject device, would be prescribed to patients and that physicians and patients were relying on them to furnish a suitable device. Further, Defendants knew, or should have known, that patients by whom the Recalled Devices would be used, such as Sharon Lis, could be and would be affected by the defective design and composition of the devices.

136. Upon information and belief, Defendants researched, designed, manufactured, tested, advertised, promoted, marketed and distributed a defective device which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiff Sharon Lis and her husband (loss of consortium), and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

137. As a direct and proximate result of Defendants' placement of the subject defective device into the stream of commerce and Plaintiff Sharon Lis' use of the product as designed, manufactured, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff Sharon Lis suffered serious physical and mental injuries including but not limited to lung cancer, debilitating injuries, harm, damages and economic loss and will continue to suffer great pain, discomfort, harm, damages and economic loss in the future as a result of being unable to attend to her ordinary affairs and she is and will remain disfigured.

138. That by reason of the foregoing, the Defendants are liable to Plaintiffs under New York's Strict Products Liability in the amount set forth in Paragraphs "113" and "114" of this Complaint.

139. That by reason of the foregoing on the part of the Defendants, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

AS AND FOR A THIRD CAUSE OF ACTION IN STRICT PRODUCTS LIABILITY – FAILURE TO WARN AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

140. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "139" of the Complaint herein with the same force and effect as if fully set forth herein.

141. Defendants had a duty to warn Plaintiff Sharon Lis regarding the defect and true risks associated with the Recalled Devices, including the subject device.

142. Upon information and belief, Defendants are liable under the theory of strict products liability. Defendants were, at all times relevant to this suit, engaged in the business of designing, manufacturing, testing, marketing, distributing and placing into the stream of commerce CPAP and BiPAP devices for sale to and for use by members of the public, including the subject device at issue in this lawsuit.

143. The subject device manufactured by Defendants reached Plaintiff Sharon Lis without substantial change and was used as directed. Upon information and belief, the subject device used by Plaintiff Sharon Lis was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Plaintiff Sharon Lis.

144. Defendants, as manufacturers of CPAP and BiPAP devices, are held to the level of knowledge of an expert in the field. Further, Defendants knew, or should have known, that warnings and other relevant information and data which they distributed regarding the defect of the device and associated health risks with the use of devices were inadequate.

145. Upon information and belief, at all times herein mentioned, Defendants designed, developed, researched, tested and knew, or should have known, about the significant cancer risks of the subject device.

146. At all times herein mentioned, Defendants advertised, promoted, marketed, sold and distributed the subject device that was used by Plaintiff Sharon Lis.

147. The subject device was expected to and did reach the usual consumers, handlers and persons coming into contact with said device without substantial change in the condition in which it was produced, manufactured, sold, distributed and marketed by the Defendants.

148. Defendants each had an independent duty and a continuing duty to warn the medical community and consumers, including Plaintiff Sharon Lis and her physician, about the significance of the risks of cancer and other health harms associated with the subject device as it became or could have become available to Defendants.

149. Plaintiff Sharon Lis used the subject device in a manner intended and foreseeable by Defendants.

150. Upon information and belief, the subject device was defective due to inadequate warnings because Defendants knew, or should have known, that the product created a significantly increased risk of cancer, among other health impacts, and failed to warn the medical community and Plaintiff's physician of the nature of such risks.

151. Defendants failed to provide adequate warnings regarding the risks of the PE-PUR Foam.

152. Upon information and belief, Defendants omitted and downplayed the significantly increased risks of cancer and other health risks associated with the Recalled Devices, including the subject device, that Defendants knew, or should have known, from previous testing and research even prior to subject device's FDA approval.

153. Upon information and belief, Defendants falsely represented to Plaintiff Sharon Lis and her physician that the subject device was safe for human use.

154. Upon information and belief, despite Defendants' obligation to unilaterally strengthen the warnings, Defendants instead chose to actively conceal this knowledge.

155. Upon information and belief, Defendants intentionally, knowingly and recklessly made these misrepresentations to induce Plaintiff's prescribing physician to prescribe and Plaintiff Sharon Lis to purchase, the Recalled subject device.

156. Plaintiff Sharon Lis and her prescribing physician did not have the same knowledge as Defendants and no adequate warning or other relevant information and data was communicated to Plaintiff Sharon Lis or her physician.

157. Among other defects, the subject device's labeling and warnings were defective because they omitted and inadequately warned of the device's risk of cancer and other health risks.

158. Upon information and belief, Defendants had information regarding the true risks but failed to warn Plaintiff Sharon Lis and her prescribing physician about the true risks stated herein and Defendants chose not to strengthen their warnings.

159. Although physicians are supposed to weigh the risks and benefits before prescribing a medical device, upon information and belief, Defendants knew that their deliberate omissions would cause physicians, including Plaintiff Sharon Lis' physician, to prescribe the subject device without being able to adequately weigh the risk of device's risk of cancer and other health risks.

160. If Defendants would have properly warned about the subject device's cancer risk and/or other health harms, Plaintiff Sharon Lis' prescribing physician would not have recommended or prescribed the subject device and Plaintiff Sharon Lis would not have purchased or used the subject device because the potential benefits of the subject device are significantly outweighed by the risk of cancer and other harms.

161. Had Defendants reasonably provided adequate warnings of cancer, such warnings would have been heeded and no healthcare professional, including Plaintiff Sharon Lis' physician, would have prescribed the subject device and no consumer, including Plaintiff Sharon Lis, would have purchased and/or used the subject device. Instead, Plaintiff's prescribing physician would have prescribed and Plaintiff Sharon Lis would have purchased and used a safer alternative device or recommended and used an alternative course of medical treatment that did not include the subject device.

162. Defendants had an obligation to provide Plaintiff Sharon Lis and Sharon Lis' physician with adequate information, data and warnings regarding the risks associated with the use of the subject device and/or that there existed safer and more or equally effective alternative devices.

163. Upon information and belief, Defendants knew that their representations to plaintiff about the Recalled Devices, including the subject device, were false in that the Recalled Devices, including the subject device, contained PE-PUR Foam that placed users like plaintiff at risk of adverse health effects from the continued inhalation of the Recalled Devices, including the subject device, which does not conform to the products' labels, packaging, advertising and statements.

164. Upon information and belief, Defendants knowingly allowed their packaging, labels, advertisements, promotional materials and websites to intentionally mislead consumers, such as Plaintiff Sharon Lis, and Plaintiff's prescribing physician.

165. Defendants marketed, promoted, distributed and sold the unreasonably dangerous and defective Recalled Devices, including the subject device, to consumers, Plaintiff Sharon Lis, and her prescribing physician without adequate warnings and other relevant information and data. Upon information and belief, through both omission and affirmative misstatements, Defendants misled Plaintiff Sharon Lis and her prescribing physician about the health risks associated with the use of the Recalled Devices, including the subject device, which resulted in injury to Plaintiff.

166. Plaintiff Sharon Lis would not have purchased, chosen, used and/or paid for all or part of the subject device and Plaintiff's prescribing physician would not have prescribed the subject device if they had known of the defect and the risks of purchasing and using the device.

167. Plaintiff Sharon Lis and Plaintiff's prescribing physician did in fact rely on these misrepresentations and omissions and Plaintiff Sharon Lis was prescribed and she purchased and used the subject device as a result of those misrepresentations and omissions. Given the deceptive

manner in which Defendants advertised, represented and otherwise promoted the Recalled Devices, including the subject device, Plaintiff's and Plaintiff's physician's reliance on Defendants' misrepresentations was justifiable.

168. By failing to provide Plaintiff Sharon Lis and her physician with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with use of the Recalled Devices, including the subject device, and/or that there existed safer and more equally effective alternative devices, Defendants breached their duty of reasonable care and safety.

169. Upon information and belief, Defendants' actions described above were performed willfully, intentionally and with reckless disregard of the life and safety of Plaintiff Sharon Lis and the public.

170. As a direct and proximate result of the subject device's defects as described herein that was placed into the stream of commerce, Plaintiff Sharon Lis developed cancer, suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has further suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost her ability to live a normal life and will continue to be so diminished in the future.

171. By reason of the foregoing, the Defendants are liable to the plaintiffs under New York Strict Products Liability in an amount set forth in Paragraphs "113" and "114" of this Complaint.

AS AND FOR A FOURTH CAUSE OF ACTION IN STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

172. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "171" of the Complaint herein with the same force and effect as if fully set forth herein.

173. Defendants are liable under the theory of strict products liability. Defendants were at all times relevant to this suit and are now engaged in the business of researching, designing, manufacturing, testing, marketing, selling, disturbing and/or placing into the stream of commerce the Recalled Devices, including the subject device, which are defective and unreasonably dangerous.

174. The subject device was expected to and did reach Plaintiff Sharon Lis without a substantial change in its condition.

175. Upon information and belief, the finished subject device deviated, in terms of construction and quality, from the specifications or planned output in a manner that made it unreasonably dangerous.

176. Upon information and belief, at all relevant times, the Recalled Devices, including the subject device, were defectively and improperly manufactured and designed by Defendants in that Defendants continued to supply consumers with the Recalled Devices despite having full knowledge that the devices posed substantial and avoidable bodily injury.

177. Upon information and belief, the foreseeable risks of the subject device were known to Defendants and could have been avoided.

178. Upon information and belief, at all relevant times, the subject device was defectively manufactured by Defendants in that its design and formulation is more dangerous than what an ordinary consumer would expect when used in an intended and reasonably foreseeable manner.

179. Upon information and belief, at all relevant times, Defendants actively deceived users that their use of the Recalled Devices posed safety risks that far outweighed any benefits.

180. Upon information and belief, the Recalled Devices, including the subject device, were defectively manufactured in that the PE-PUR Foam comprising part of the devices can

degrade into particles that enter the devices' air pathway and can off-gas certain chemicals. These characteristics cause, among other problems, cancer. Plaintiff Sharon Lis and other similarly situated consumers were unknowingly subjected to receiving different doses of toxins, carcinogens and other deleterious components and contaminants when using the Recalled Devices.

181. As a direct and proximate result of the defective manufacture of the subject device placed into the stream of commerce, Plaintiff Sharon Lis suffered and will continue to suffer damages for which she is entitled to recovery.

182. By reason of the foregoing, the Defendants are liable to the Plaintiff in an amount set forth in Paragraphs numbered "113" and "114" of this Complaint.

AS AND FOR A FIFTH CAUSE OF ACTION IN FRAUD AND MISREPRESENTATION AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

183. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "182" of the Complaint herein with the same force and effect as if fully set forth herein.

184. Upon information and belief, an inspection of Philips' internal company records conducted by the Food and Drug Administration (hereinafter "FDA") during August through November, 2021 reflects the following:

- As early as 2015, Philips was made aware that the polyester polyurethane foam in its devices was degrading during normal use;
- In 2016, Philips learned that the polyester polyurethane foam in its machines could degrade and break down in as little as one year of use;
- Records of users of Philips' devices reflect that since 2008, Philips received notice of over 222,000 complaints of degradation of the polyester polyurethane foam across all Philips' products containing the affected foam;

- By 2019, Philips was aware that biological risk assessments conducted in the field in response to reports/complaints regarding degraded and broken down polyester polyurethane foam in various CPAP products indicated the potential for cancer and other biological and toxicological risks from exposure to the degraded polyester polyurethane foam;
- As early as 2020, internal company documents revealed that the subject device failed emissions testing, exceeding tolerable limits, for the release of volatile organic compounds due to the foam's degrading.

185. As set forth above in Plaintiffs' "Factual Allegations", upon information and belief, Plaintiffs allege that Philips made affirmative misrepresentations regarding the safety and effectiveness of the subject device and omitted and withheld material safety information regarding the subject device to Plaintiff and her prescribing physician. Upon information and belief, among other wrongful conduct identified above, Philips fraudulently misrepresented the safety of its subject devices and failed to inform users and/or the medical profession that these devices containing polyester based polyurethane were breaking down into toxic particles that could be inhaled by users of these breathing machines.

186. Upon information and belief, plaintiff further alleges that during this period of time, while knowing that its polyester foam insulation devices were breaking down and releasing toxic particles that could be breathed in by the user, Philips failed to warn and continued to fraudulently misrepresent the safety of its products to users and the medical profession all to the detriment of plaintiff and others similarly situated.

187. Defendants had a duty to exercise reasonable care to those to whom they provided device information about the Recalled Devices and to all those relying on the information

provided, including Plaintiff Sharon Lis, her healthcare providers and the public in general that the devices had been tested and found to be safe and effective for treating sleep apnea.

188. Upon information and belief, Defendants, in the course of selling the Recalled Devices, supplied information about the devices through television commercials, advertisements, marketing campaigns, sales representatives, labeling and warnings.

189. Defendants breached their duty by misrepresenting the subject device's safety to the medical and healthcare community, to Plaintiff Sharon Lis and Plaintiff's prescribing physician.

190. Defendants failed to exercise reasonable care because their goal should have been to put safety before their profits by providing individuals with the realistic risks and expectations that the Recalled Devices could cause cancer and other serious injuries.

191. Defendants' representations were made without properly conducting sufficient testing and by providing insufficient warnings about the Recalled Devices' potential risks.

192. Defendants' false representations that the Recalled Devices were safe for consumers and their failure to disclose material past and existing facts of the Recalled Devices' risk of cancer were made or omitted with the intent to induce Plaintiff Sharon Lis and her prescribing physician to rely upon those facts or omissions.

193. Plaintiff Sharon Lis and her physician were unaware and did not know that the subject device was unsafe for the purpose of treating sleep apnea because it caused a significant increased risk of cancer until after she had been exposed to carcinogenic particles and gasses.

194. Plaintiff Sharon Lis and her physician justifiably relied upon the false representations and omissions of Defendants.

195. Had Defendants provided adequate warnings of cancer and other serious injuries, such warnings would have been heeded by plaintiff and her prescribing physician.

196. Had Defendants reasonably provided adequate warnings of cancer, such warnings would have been heeded and no healthcare professional, including Plaintiff Sharon Lis' physician, would have prescribed the subject device and no consumer, including Plaintiff Sharon Lis, would have purchased and/or used the subject device. Instead, Plaintiff's prescribing physician would have prescribed and Plaintiff Sharon Lis would have purchased and used a safer alternative device or recommended and used an alternative course of medical treatment that did not include the subject device.

197. As a direct and proximate result of the foregoing acts and omissions, Plaintiff Sharon Lis was caused to suffer serious and dangerous side effects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications and fear of redeveloping cancer and is entitled to an amount of damages as set forth in Paragraphs "113" and "114" of this Complaint. Plaintiffs do not allege a claim or cause of action for fraud on the FDA.

AS AND FOR A SIXTH CAUSE OF ACTION IN BREACH OF EXPRESS WARRANTY AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

198. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "197" of the Complaint herein with the same force and effect as if fully set forth herein.

199. At all relevant times, Defendants, through their advertising and promotional materials, expressly and impliedly warranted and affirmed that the subject devices' purpose was to offer a reasonably safe treatment for sleep apnea and similar health problems.

200. Upon information and belief, Defendants touted the subject devices as safe, despite knowingly having never adequately researched or tested the devices to assess their safety before placing the devices on the market and promoting them to consumers.

201. Defendants intended to make Plaintiff Sharon Lis and the general public believe the subject devices were safe.

202. Upon information and belief, Defendants knowingly mislead Plaintiff Sharon Lis and the general public to believe the subject devices were safe for use, despite knowing that the devices could lead to serious injuries, all of which Defendants knew, or by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff Sharon Lis would be victim to.

203. Upon information and belief, at all relevant times, Defendants had knowledge of the hazards and health risks posed by the Recalled Devices when used.

204. Upon information and belief, at all relevant times, Defendants willfully failed to disclose the defects and health risks of the Recalled Devices to Plaintiff Sharon Lis and the consuming public.

205. Plaintiff Sharon Lis relied, to her detriment, on the information publicized by Defendants.

206. In reliance upon these warranties as to the safety of the subject device by Defendants, Plaintiff Sharon Lis acquired/purchased and used the subject device, believing that the subject device was inherently safe.

207. Plaintiff Sharon Lis notified Defendants of the breach.

208. As a direct and proximate result of the foregoing acts and omissions, Plaintiff Sharon Lis suffered and will continue to suffer damages in an amount as set forth in Paragraphs "113" and "114" for which she is entitled to recovery.

AS AND FOR A SEVENTH CAUSE OF ACTION UNDER IMPLIED WARRANTY OF MERCHANTABILITY AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

209. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "208" of the Complaint herein with the same force and effect as if fully set forth herein.

210. Upon information and belief, at all relevant times, Defendants have been merchants in regard to the recalled devices, including the subject device, they created and sold to consumers.

211. Upon information and belief, Defendants breached their implied warranty of merchantability since the subject devices were defective when created and designed and do not conform with the promises represented on their labels.

212. Upon information and belief, Defendants failed to comply with merchantability requirements, as the subject devices do not achieve the ordinary purposes they advertise: a healthy treatment for respiratory conditions such as sleep apnea.

213. Beyond Defendants' own direct sales of the subject devices, Plaintiff Sharon Lis and other consumers are third-party beneficiaries of Defendants' agreements with their distributors, dealers and sellers for the distribution, dealing and sale of the Recalled Devices to consumers. Plaintiff Sharon Lis and consumers are the intended beneficiaries of Defendants' implied warranties since the Recalled Devices are manufactured with the express and intended purpose of selling the devices to consumers.

214. As a direct and proximate result of Defendants' breach of their implied warranties of merchantability regarding the subject device, Plaintiff Sharon Lis was damaged because, had she been aware of the unmerchantable condition of the subject device, she would have not acquired/purchased/used the subject device and not suffered injuries and damages from its use.

215. As a direct and proximate result of the foregoing acts and omissions, Plaintiff Sharon Lis suffered and will continue to suffer damages in an amount as set forth in Paragraphs "113" and "114" for which she is entitled to recovery.

AS AND FOR AN EIGHTH CAUSE OF ACTION UNDER LOSS OF CONSORTIUM AGAINST THE NAMED DEFENDANTS, PLAINTIFF ALLEN LIS ALLEGES:

216. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "215" of the Complaint herein with the same force and effect as if fully set forth herein.

217. At all relevant times, Plaintiff Allen Lis was and still is the lawful spouse of Plaintiff Sharon Lis and as such was entitled to her services.

218. At all relevant times, Plaintiff Allen Lis has been deprived of the services, society, companionship, consortium and support of his wife, Plaintiff Sharon Lis, all to his damage.

219. That by reason of the foregoing, Plaintiff Sharon Lis was compelled to seek and obtain medical aid and attention and Plaintiff Allen Lis did necessarily pay and become liable therefor, for medicines and medical care and upon information and belief, Plaintiff Sharon Lis will necessarily incur further similar expenses.

220. That by reason of the foregoing, Plaintiff Allen Lis has been damaged in an amount that exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

WHEREFORE, Plaintiffs demand judgment against the Defendants in the First, Second, Third, Fourth, Fifth, Sixth, Seventh and Eighth Causes of Action in an amount exceeding the jurisdictional limits of all other courts which would otherwise have jurisdiction over this matter; punitive damages in a sum of money to be determined by the trier of fact; and for such other and further relief as may be just and proper, together with the costs and disbursements of this action.

DEMAND FOR JURY TRIAL

221. Plaintiffs demand a jury trial on all counts in this Verified Complaint.

Dated this 10th day of August, 2023.

Michael A. Ponterio, Esq.
Lipsitz, Ponterio & Comerford LLC
424 Main Street, Suite 1500
Buffalo, NY 14202
Phone: (716) 849-0701
Fax: (716) 849-0708

Connor G. Sheehan, Esq.*
Texas Bar No. 24046827
csheehan@dunnsheehan.com
DUNN SHEEHAN LLP
5910 N. Central Expressway, Suite 1310
Dallas, Texas 75206
Phone: (214) 866-0077
Fax: (214) 866-0070
**pro hac vice application forthcoming*

Attorneys for Plaintiffs

VERIFICATION

STATE OF NEW YORK)
COUNTY OF ERIE) SS.:
CITY OF BUFFALO)

The undersigned, an attorney admitted to practice in the courts of the State of New York, shows: that deponent is a member of the firm of LIPSITZ, PONTERIO & COMERFORD LLC, the attorneys of record for the plaintiffs in the within action; that deponent has read the foregoing Verified Complaint and knows the contents thereof; that the same is true to deponent's own knowledge, except as to those matters therein stated to be alleged upon information and belief and as to those matters deponent believes it to be true. Deponent further says that the reason this verification is made by deponent and not by plaintiffs, SHARON LIS and ALLEN LIS, is because said plaintiffs are not in Erie County which is the county where deponent has his principal office.

The grounds of deponent's belief as to all matters not stated upon deponent's knowledge are as follows: records, reports and correspondence in deponent's file.

The undersigned affirms that the foregoing statements are true, under the penalties of perjury.

Dated: August 10, 2023

Michael A. Ponterio

MICHAEL A. PONTERIO, ESQ.

EXHIBIT C

Notice of Service of Process

null / ALL
Transmittal Number: 27487498
Date Processed: 08/17/2023

Primary Contact:
Barbara Bickford
Philips North America LLC
222 Jacobs St
Fl 3
Cambridge, MA 02141-2289

Entity:	Philips North America LLC Entity ID Number 1920741
Entity Served:	Philips North America LLC
Title of Action:	Sharon Lis vs. Koninklijke Philips N.V.
Matter Name/ID:	Sharon Lis vs. Koninklijke Philips N.V. (14485630)
Document(s) Type:	Summons/Complaint
Nature of Action:	Product Liability
Court/Agency:	Niagara County Supreme Court, NY
Case/Reference No:	E180656/2023
Jurisdiction Served:	Delaware
Date Served on CSC:	08/17/2023
Answer or Appearance Due:	30 Days
Originally Served On:	CSC
How Served:	Personal Service
Sender Information:	Lipsitz, Ponterio & Comerford LLC 716-849-0701

Information contained on this transmittal form is for record keeping, notification and forwarding the attached document(s). It does not constitute a legal opinion. The recipient is responsible for interpreting the documents and taking appropriate action.

To avoid potential delay, please do not send your response to CSC

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NIAGARA

----------x

SHARON LIS and
ALLEN LIS, her spouse

Plaintiff/Petitioner,

- against -

Index No. E180656/2023

KONINKLIJKE PHILIPS N.V., et al.

Defendant/Respondent.

----------x

NOTICE OF ELECTRONIC FILING
(Consensual Case)
(Uniform Rule § 202.5-b)

You have received this Notice because:

1) The Plaintiff/Petitioner, whose name is listed above, has filed this case using the New York State Courts E-filing system ("NYSCEF"), and

2) You are a Defendant/Respondent (a party) in this case.

- **If you are represented by an attorney:**
  Give this Notice to your attorney. (Attorneys: see "Information for Attorneys" pg. 2).

- **If you are not represented by an attorney:**
  You will be served with all documents in paper and you must serve and file your documents in paper, unless you choose to participate in e-filing.

  If you choose to participate in e-filing, you must have access to a computer and a scanner or other device to convert documents into electronic format, a connection to the internet, and an e-mail address to receive service of documents.

  The **benefits of participating in e-filing** include:

  - serving and filing your documents electronically
  - free access to view and print your e-filed documents
  - limiting your number of trips to the courthouse
  - paying any court fees on-line (credit card needed)

  To register for e-filing or for more information about how e-filing works:

  - visit: www.nycourts.gov/efile-unrepresented or
  - contact the Clerk's Office or Help Center at the court where the case was filed. Court contact information can be found at www.nycourts.gov

To find legal information to help you represent yourself visit www.nycourthelp.gov

Information for Attorneys

An attorney representing a party who is served with this notice must either consent or decline consent to electronic filing and service through NYSCEF for this case.

Attorneys registered with NYSCEF may record their consent electronically in the manner provided at the NYSCEF site. Attorneys not registered with NYSCEF but intending to participate in e-filing must first create a NYSCEF account and obtain a user ID and password prior to recording their consent by going to www.nycourts.gov/efile

Attorneys declining to consent must file with the court and serve on all parties of record a declination of consent.

For additional information about electronic filing and to create a NYSCEF account, visit the NYSCEF website at www.nycourts.gov/efile or contact the NYSCEF Resource Center (phone: 646-386-3033; e-mail: nyscef@nycourts.gov).

Dated: August 10, 2023

Michael A. Ponterio, Esq.
Name

LIPSITZ, PONTERIO & COMERFORD, LLC
Firm Name

424 Main Street, Suite 1500

Buffalo, New York 14202
Address

(716) 849-0701
Phone

map@lipsitzponterio.com
E-Mail

TO: ALL NAMED DEFENDANTS

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NIAGARA

SHARON LIS and
ALLEN LIS, her spouse
5384 County Road 36
Honeoye, NY 14471

Plaintiffs,

vs.

KONINKLIJKE PHILIPS N.V.
Philips Center
Amstelplein 2,
1096 BC Amsterdam
The Netherlands

PHILIPS NORTH AMERICA LLC
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

PHILIPS RS NORTH AMERICA LLC
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

PHILIPS HOLDING USA, INC.
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

PHILIPS HEALTHCARE
222 Jacobs Street
Cambridge, MA 02141

HEALTH SYSTEM SERVICES, LTD.
6867 Williams Road
Niagara Falls, NY 14304

Defendants.

SUMMONS

Plaintiffs designate Niagara County as the place of trial

The basis of venue is the residence of a defendant

Defendant, Health System Services, Ltd., resides at 6867 Williams Road Niagara Falls, NY

County of Niagara

TO THE ABOVE-NAMED DEFENDANTS:

YOU ARE HEREBY SUMMONED to answer the Verified Complaint in this action and to serve a copy of your answer, or, if the Verified Complaint is not served with this Summons, to

serve a notice of appearance on the Plaintiffs' Attorneys within 20 days after the service of this Summons, exclusive of the day of service (or within 30 days after the service is complete if this Summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the Verified Complaint.

Dated: Buffalo, New York
August 10, 2023

Michael A. Ponterio, Esq.
Lipsitz, Ponterio & Comerford, LLC
424 Main Street, Suite 1500
Buffalo, NY 14202
Phone: 716.849.0701
Fax: 716.849.0708

Connor G. Sheehan*
Texas Bar No. 24046827
csheehan@dunnsheehan.com
DUNN SHEEHAN LLP
5910 N. Central Expressway, Suite 1310
Dallas, Texas 75206
Phone: 214.866.0077
Fax: 214.866.0070
**pro hac vice application forthcoming*

Attorneys for Plaintiffs

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NIAGARA

SHARON LIS and
ALLEN LIS, her spouse,

Plaintiffs,

VERIFIED COMPLAINT

vs.

KONINKLIJKE PHILIPS N.V.,
PHILIPS NORTH AMERICA LLC,
PHILIPS RS NORTH AMERICA LLC,
PHILIPS HOLDING USA, INC.,
PHILIPS HEALTHCARE,
HEALTH SYSTEM SERVICES, LTD.,

Defendants.

Plaintiffs SHARON LIS and ALLEN LIS ("Plaintiffs"), by and through their counsel, file this Verified Complaint against Defendants KONINKLIJKE PHILIPS N.V. ("Royal Philips"), PHILIPS NORTH AMERICA LLC ("Philips NA"), PHILIPS RS NORTH AMERICA LLC ("Philips RS"), PHILIPS HOLDING USA, Inc. ("PHUSA"), PHILIPS HEALTHCARE ("PHC" and, collectively with Royal Philips, Philips NA, Philips RS, and PHUSA, "Philips"), and HEALTH SYSTEM SERVICES, LTD. ("HSS" and, collectively with Philips, "Defendants").

INTRODUCTION

1. Plaintiff Sharon Lis ("Sharon") brings this action on behalf of herself for personal injuries that she sustained as a purchaser and long-time user of a defective Philips DreamStation Auto Continuous Positive Airway Pressure mechanical ventilator device (the "DreamStation CPAP machine" or "subject device") that contains polyester-based polyurethane sound abatement foam ("PE-PUR Foam"). On June 14, 2021, Phillips recalled the DreamStation CPAP machine due to the PE-PUR Foam's known propensity to break down, resulting in small pieces of foam and invisible chemicals being breathed in or swallowed by the user resulting in serious and permanent

injuries. Plaintiff Allen Lis ("Allen") brings a derivative claim for loss of consortium arising from injuries relating to those sustained by his lawful spouse, Sharon.

2. Philips develops, manufactures, markets, imports, sells, and distributes a variety of products for sleep and home respiratory care. Philips also develops, manufactures, markets, imports, sells, and distributes a variety of ventilator devices for patients with respiratory conditions.

3. On April 26, 2021, Philips publicly announced its determination that there were risks that the PE-PUR Foam used in certain CPAP, Bi-Level PAP, and mechanical ventilator devices manufactured by Philips – specifically including the subject device used by Sharon – will degrade or off-gas under certain circumstances.

4. On June 14, 2021, Royal Philips issued a recall ("Recall Notice") in the United States of its CPAP, Bi-Level PAP, and mechanical ventilator devices containing PE-PUR Foam – specifically including the subject device. In particular, Philips disclosed for the first time its determination that (a) the PE-PUR Foam in those devices emits volatile organic compounds which, when inhaled, can result in serious adverse health effects, including but not limited to acute respiratory distress syndrome (ARDS), lung disease, lung damage, chemical poisoning, heart attack, heart failure, kidney disease, reactive airway disease (RAD), respiratory failure, severe inflammation, and multiple types of cancer.

5. In total, Philips announced that "between 3 million and 4 million" devices were targeted in the recall. In its Recall Notice, Philips advised of serious health risks related to the PE-PUR Foam and recommended that patients using the recalled CPAP and Bi-Level PAP devices immediately discontinue use of the devices and consult with their physicians regarding alternative ventilator options.

6. On or about April 11, 2018 – more than three years before Philips issued the Recall Notice – the subject device used by Plaintiff Sharon Lis was distributed by HSS. This device, the Philips' subsequently-recalled devices, the DreamStation CPAP Machine, Serial No. J2125235256ED, was used by Plaintiff Sharon Lis to treat her obstructive sleep apnea. Sharon, a 55-year-old lifetime nonsmoker, used the CPAP device on a regular basis from the date she acquired it in early 2018 until approximately June 2021.

7. On or about August 11, 2022, as a result of her extended usage of the subject device, Sharon was diagnosed with bronchogenic carcinoma, a cancerous tumor originating in her lung along the right middle portion of her chest that can only be removed surgically. On or about November 2, 2022, Sharon underwent a right middle lobectomy to remove a section of the carcinoid tumor in her lung. The surgery resulted in only half of the cancerous tumor being removed due to its location on her lung.

8. As a direct and proximate result of her long-term use of Defendants' defective and dangerous device, Sharon has suffered and continues to suffer from severe symptoms of lung cancer, requiring continuous medical treatments and resulting in severe associated pain, suffering, and emotional distress.

9. Among other things, Sharon must have frequent scans of her body and blood work to determine if the cancer has grown or spread, which will result in a second surgery to remove the remainder of her cancerous lung. She is prescribed several pain medications to be able to tolerate the extreme pain that this cancer causes.

10. As a direct and proximate result of Defendants' wrongful conduct alleged herein, Sharon has suffered, continues to suffer, and will for the foreseeable future suffer from serious and dangerous side effects as a result of the cancer, as well as other severe and personal injuries which

are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and requires lifelong medical treatment and monitoring.

PARTIES

11. Plaintiffs are citizens of the State of New York, residing in Ontario County. Plaintiff Allen Lis is the lawful wedded spouse of Plaintiff Sharon Lis.

12. Upon information and belief, Defendant Royal Philips is a public limited liability company established under the laws of The Netherlands, having its principal executive offices at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the parent company of Philips North America, LLC and Philips RS North America, LLC.

13. Upon information and belief, Royal Philips controls Philips NA and Philips RS in the manufacturing, selling, distributing and supplying of the recalled CPAP, Bi-Level PAP and mechanical ventilator devices, including but not limited to the DreamStation CPAP Machine used by Plaintiff.

14. Upon information and belief, Defendant Philips NA is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly owned subsidiary of Royal Philips.

15. Upon information and belief, Defendant Philips RS is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS is a wholly owned subsidiary of Royal Philips. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.

16. Upon information and belief, Defendant PHUSA is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. PHUSA is a wholly owned subsidiary of Royal Philips.

17. Upon information and belief, Defendant Philips Healthcare is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Cambridge, Massachusetts 02141. That at all times hereinafter mentioned, it has been engaged in the sale, distribution and marketing of medical equipment including, but not limited to, the Philips DreamStation CPAP machine.

18. Upon information and belief, that at all times hereinafter mentioned, the Defendant, Health System Services, Ltd., was and still is a New York domestic business corporation duly organized under §402 of New York State Business Corporation Law. That at all times hereinafter mentioned, the Defendant, Health System Services, Ltd., has its principal place of business in Niagara Falls, New York. Venue is in Niagara County pursuant to CPLR 503 based upon Defendant, Health System Services, Ltd.'s principal place of business located at 6867 Williams Road, Niagara Falls, New York 14304, Niagara County.

JURISDICTION AND VENUE

19. Upon information and belief, at all relevant times, Defendant Royal Philips conducted business in the State of New York; transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; derived substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury to a person or property with the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

20. Upon information and belief, at all relevant times, Defendant Royal Philips shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times, Defendant Royal Philips was engaged in the business of designing, manufacturing, distributing, selling and marketing the subject device.

21. Upon information and belief, at all relevant times, Defendant Royal Philips NA transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; manufactured, distributed, designed and sold, the subject device with the serial number J2125235256ED.

22. Upon information and belief, at all relevant times, Defendant Philips NA is a Delaware corporation with its principal place of business located in Cambridge, Massachusetts. Defendant Philips NA is a wholly owned subsidiary of Defendant Royal Philips. Upon information and belief, Defendant Philips NA manages the operation of Defendant Royal Philips' various lines of business, including Philips RS. The sole member of Defendant Philips NA is Defendant PHUSA, which is a Delaware corporation with its principal place of business place of business in Cambridge, Massachusetts.

23. Upon information and belief, at all relevant times, Defendant Philips NA did business and contracted to supply goods or services in the State of New York; derived substantial profits from its sales in the State of New York; and committed a tortious act within the State of New York causing injury to a person or property within the State of New York.

24. Upon information and belief, at all relevant times, Defendant Philips NA was engaged in the business of designing, manufacturing, distributing, selling and marketing the subject device; shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce; transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302

25. Upon information and belief, at all relevant times, Defendant PHUSA is a Delaware corporation with its principal place of business in Cambridge, Massachusetts. Defendant PHUSA is a holding company that is the sole member of Defendant Philips NA.

26. Upon information and belief, at all relevant times, Defendant PHUSA shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times, Defendant PHUSA transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; derived substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury to a person or property with the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

27. Upon information and belief, at all relevant times, Defendant Philips RS is a Delaware corporation with its principal place of business in Pittsburgh, Pennsylvania. Defendant Philips RS was formerly operated under the business name Respironics, Inc. Defendant Royal Philips acquired Respironics, Inc. in 2008.

28. Upon information and belief, at all relevant times, Defendant Philips RS shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times, Defendant Philips RS was engaged in the business of designing, manufacturing, distributing, selling and marketing the subject device.

29. Upon information and belief, at all relevant times, Defendant Philips RS transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; did business in the State of New York; derived substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury

to a person or property within the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

30. Upon information and belief, at all relevant times, Defendant PHC is a Delaware company with its principal place of business in Cambridge, Massachusetts. At all relevant times, Defendant PHC was a foreign corporation, organized and existing pursuant to and by virtue of the laws of the State of Delaware that has authorization to do business in the State of New York.

31. Upon information and belief, at all relevant times, Defendant PHC shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times herein, Defendant PHC was engaged in the business of distributing, selling, promoting, advertising and marketing the subject device.

32. Upon information and belief, at all relevant times, Defendant PHC was and still is a corporation conducting business in the State of New York; Defendant PHC transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; derived substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury to a person or property within the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

33. Upon information and belief, Defendant HSS is a New York company with its principal place of business in Niagara Falls, New York. Defendant HSS distributed, shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times, Defendant HSS was engaged in the business of distributing, selling, promoting, advertising and marketing the subject device; was and still is a corporation conducting business in the State of New York; contracted to supply goods or services in the State of New York; derived

substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury to a person or property with the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

34. Upon information and belief, at all relevant times, Defendants (other than HSS) were the mere alter egos or instrumentalities of each other. There is such a unity of interest and ownership between Defendants that the separate personalities of their entities ceased to exist. Defendants (other than HSS) operated as a single enterprise, equally controlled each other's business affairs, commingled their assets and funds, disregarded corporate formalities and used each other as a corporate shield to defeat justice, perpetuate fraud and evade contractual and/or tort liability.

35. Upon information and belief, at all relevant times, Defendants acted in all respects as agents or apparent agents of one another. Upon information and belief, at all relevant times, Defendants acted in concert in the designing, manufacturing, marketing, promoting, advertising and selling of devices for the treatment of obstructive sleep apnea, including the subject device. Defendants combined their property and labor in a joint undertaking for profit, with rights of mutual control over each other, rendering them jointly liable to Plaintiffs.

36. Upon information and belief, Defendants' actions in marketing, distributing and selling their devices in New York should have led them to reasonably anticipate being brought into Court in New York.

37. Upon information and belief, Defendants have sufficient "minimum contacts" with New York that subjecting them to personal jurisdiction in New York does not offend traditional notions of fair play and substantial justice.

38. As detailed below, upon information and belief, Plaintiff Sharon Lis, age 55, suffered injuries from the subject device that Defendants negligently designed and/or

manufactured, sold and distributed. Thus, Defendants committed a tort in New York that caused injuries in New York and the Court has personal jurisdiction over Defendants under New York State's Long Arm Statute.

39. Upon information and belief, this Court has personal jurisdiction over Defendants Royal Philips, Philips NA, Philips RS, PHUSA, PHC and HSS because of their systematic and continuous contacts with New York as well as their maintenance of a registered agent for service of process in New York. Federal diversity jurisdiction does not exist because Defendant HSS is a resident and corporate citizen of New York with its headquarters located in Niagara County, New York.

40. This Court is a proper venue for this civil action because Defendant HSS has its principal place of business in Niagara County at 6867 Williams Road, Niagara Falls, New York and committed the tortious acts at issue in this Complaint in Niagara County, New York and other locations in New York. This Court's exercise of personal jurisdiction over Defendants comports with due process.

FACTUAL ALLEGATIONS

The Philips DreamStation CPAP Machine

41. Obstructive sleep apnea ("OSA") is a sleeping disorder in which breathing is disrupted temporarily during sleep periods when breathing stops or becomes very shallow. OSA is associated with fatigue, daytime sleepiness, interrupted sleep, or snoring, among other symptoms.

42. CPAP therapy helps treat sleep apnea by preventing the person's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

43. Bi-PAP therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air pressure in an individual's airway.

44. At all relevant times, Defendants developed, manufactured, marketed, sold, and distributed a lineup of CPAP and BiLevel PAP devices under the Philips "Sleep & Respiratory Care" portfolio. These devices are designed to assist individuals with a number of sleep, breathing and other respiratory conditions, including OSA.

45. Philips' flagship CPAP/BiPAP machine product family is known as the "DreamStation" family line, which includes the original DreamStation, launched in October 2015 and the DreamStation Go (a travel version). Phillips sold DreamStation products through its subsidiary Respironics, that Philips acquired in 2008.

46. Philips used PE-PUR Foam in the subject device even though it was widely known that this foam is susceptible to hydrolysis.[1] Philips brought the subject device to market through the FDA's 510(k) clearance process, which is less stringent than the FDA's Pre-Market Approval ("PMA") application process. Having placed the subject device on the market, Philips assumed various duties under federal and state law, including the duty to investigate complaints and injuries and report adverse events. Philips sold the subject device as a "clinically proven" treatment for sleep disorders, exposing users of the subject device such as Sharon at the known (to Defendants) and undisclosed risk of serious and debilitation injury. The subject device failed to comply with "current good manufacturing practice" requirements ("GMPs") and other obligations imposed by FDA regulations. For example, the PE-PUR Foam in the subject device degrades and exposes patients to toxic particles and VOCs, some of which are known or suspected carcinogens.

[1] Poly*ether* polyurethan foam, which is less prone to hydrolysis, was an available safer alternative.

47. Since 2008, Philips has received hundreds of thousands of complaints of foam degradation in the subject devices. Instead of acting, Philips turned a blind eye to the problem and actively concealed it.

Philips Knew Of The Dangers Of Pe-Pur Foam Since At Least 2015

48. In 2021, an FDA investigation concluded that Philips knew as early as 2015 – *i.e.*, three years before Sharon acquired the DreamStation CPAP machine that ultimately caused her cancer – that Defendants' CPAP machines were unsafe:

> Beginning in 2015, Philips received data from a variety of sources regarding degradation of the PE-PUR foam contained within the recalled devices, including complaints, test reports, information from suppliers, and information from another entity owned by Philips' parent company. Philips failed to adequately evaluate this data and incorporate it into its CAPA [Corrective and Preventive Actions] system for further investigation and potential mitigation, as required by current good manufacturing practice requirements codified in 21 C.F.R. § 820.100.[2]

49. The FDA's determination was based in part on twenty-one (21) site inspections of Philips' Murrysville, Pennsylvania facility between August 26, 2021, and November 9, 2021. The lead FDA investigator, Katelyn A. Staub-Zamperini, memorialized the agency's finding in a 28-page FDA, 483 Report issued on November 9, 2021.[3]

50. In connection with its investigation, the FDA learned that Philips had received numerous complaints from customers about degradation of the foam in its Recalled Devices from at least as early as 2008:

> [A] query of your firm's consumer complaints from 01/01/2008 to current, for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black, **resulted in over 222,000 complaints, and over 20,000 of which occurred between 2008 to 2017 and involved Trilogy devices.** Additionally, your firm performed a foam related complaint data analysis in April 2021 on complaints confirmed to be related to or involve foam degradation issues. The raw complaint data documents that **30 Trilogy related complaints were received from 2014 to**

[2] https://www.fda.gov/media/158129/download (last accessed June 16, 2022) ("518(b) Notice"), at 6.
[3] A 483 Report is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. A redacted version of the 483 report is available here: https://www.fda.gov/media/l 54244/download (last accessed June I6, 2022).

2017, and 1,254 related complaints were received across all products containing the affected foam, from 2014 to 2021.[4]

51. The FDA also concluded that "[n]o formal investigation, risk analysis, or CAPA[5] were initiated, performed, or documented [by or on behalf of Philips], in response to the at least 222,000 complaints that could potentially be related to foam degradation and received from 2008 to 2017."[6] Further, the FDA determined that Philips "was made aware of polyester polyurethane foam degradation issues in/around October 2015 . . ."[7]

52. The FDA also found that Philips' analysis of consumer complaints was defective in that it "was not adequately performed to identify or detect quality problems";[8] that "potential foam degradation in Trilogy ventilator devices is not an isolated incident, and you [Philips] also have not documented a detailed rationale for why harm is not likely to occur again, as required by your Health Hazard Evaluation's instructions";[9] and that Philips' "risk analysis is inadequate or was not performed when appropriate or within an appropriate time frame of your firm becoming aware" of these issues.[10]

53. On May 2, 2022, the FDA issued a formal notice to Philips pursuant to Section 518(b) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360h(b) (the "518(b) Notice").[11]

54. The 518(b) Notice stated that "there is sufficient evidence for FDA to determine that the devices subject to the recall present an unreasonable risk of substantial harm to the public health" and "that there are reasonable grounds to believe that the recalled devices that Philips

[4] 483 Report at 12 (emphasis added).
[5] A Corrective and Preventative Action ("CAPA") refers to procedures that medical device manufactures must follow to identify and attempt to correct when a quality problem is detected. *See* 21 C.F.R. § 820.100.
[6] *Id.* at 16.
[7] 483 Report at 18.
[8] 483 Report at 16.
[9] *Id.* at 13.
[10] *Id.* at 3.
[11] https://www.fda.gov/media/158129/download (last accessed June 16, 2022).

manufactured after November 2015 were not properly manufactured with reference to the state of the art as it existed at the time of the devices' manufacture."[12]

55. The FDA also concluded that "[t]his risk is not the unavoidable byproduct of current ventilator, CPAP machine, and BiPAP machine technologies. Indeed, Philips and its competitors market ventilators, CPAP machines, and BiPAP machines that do not use PE-PUR Foam."[13]

56. The FDA's findings are directly applicable to the Philips DreamStation CPAP machine that caused Sharon's lung cancer.

57. Knowing about these safety issues with the PE-PUR Foam, Philips tested the foam material used in its Recalled Devices. According to the FDA, "this testing spoke only to the limited finding that in the case of the [redacted] foam samples 'returned from service in a Pacific rim location,' spectroscopy results were 'consistent with an environmental/chemical exposure causing base polymer cleavage and embrittlement of the material."[14] Nonetheless, based on the results of this limited testing, Philips concluded that no escalation to a CAPA process was required.

58. Philips was alerted to more warning signs of the dangers of the subject device as it continued to ask its supplier about the properties of the PE-PUR Foam it was continuing to put in medical devices that millions of its customers, including Sharon, were breathing through nightly to help their sleeping disorders with no way to know that they were exposing themselves to deadly respiratory conditions and cancers.

Philips Opened An Internal Investigation Into Foam Degradation In Mid-2018

59. On April 12, 2018, almost to the day when Sharon acquired and began to use the subject device, Philips opened a precursor to a formal CAPA, referred to by Philips as a CAPA

[12] *Id.* at 2.
[13] *Id.* at 6
[14] 518(b) Notice at 7.

INV 0988, "to investigate complaints related to potential foam degradation for the Trilogy devices in Australia and to determine what actions should be taken."[50]

60. On June 20, 2018, Philips closed CAPA INV 0988.[15] According to the FDA, Philips implemented "a preventative maintenance procedure for Trilogy devices, but Philips did not verify the effectiveness of this measure."[16]

61. The FDA pointed out that Philips' informal CAPA INV[17] related to these Trilogy devices did "not include, investigate, or examine all of your firm's CPAP and BiPAP medical devices, which also include similar air path assemblies and/or the affected polyester polyurethane foam, which is susceptible to degradation."[18] But Philips had acknowledged to the FDA that it had "received approximately eighty complaints related to foam degradation, **on non-Trilogy ventilator devices,** from 2014 to 2017."[19]

62. The FDA concluded that Philips had not "adequately established" procedures for initiating CAPA procedures.[20] Specifically, the FDA faulted Philips for not initiating a "formal" CAPA after receiving "various complaints alleging foam degradation in Trilogy ventilator devices" and then closing its informal investigation just two months later without "verify[ing] the effectiveness" of the limited "preventative maintenance procedure for Trilogy devices."[21]

63. Philips continued to receive more information that suggested that the PE-PUR Foam was prone to degradation. According to the FDA, "[a] follow-up email amongst your firm's [Philips'] personnel, dated 08/24/2018, states that testing confirmed that the affected foam breaks

---

[15] 483 Report at 15.
[16] 518(b) Notice at 8.
[17] The 483 Report explained that Philips's practice at the time was to first open CAPA requests- called "CAPA INVs"-as a precursor to a formal CAPA, but this could only occur if approved by a "CAPA Review Board" or delegate. *See* 483 Report at 14-15.
[18] *Id.* at 15.
[19] *Id.* at 16 (emphasis supplied).
[20] *Id.* at 15.
[21] 518(b) Notice at 8.

down in high heat and high humidity environments, which concurred with Trilogy ventilator related complaints . . . ."[22]

64. Nonetheless, Philips continued manufacturing and selling the Recalled Devices containing PE-PUR Foam and failed to warn users such as Sharon of the known risks of serious injury from continuing to use the subject device.

Philips Opened A Formal CAPA In 2019

65. In June 2019, Philips finally initiated a formal CAPA, numbered CAPA 7211, related to the issues associated with the PE-PUR Foam. But as the FDA explains:

> Even then, that CAPA failed to evaluate all relevant data. Philips' search of FDA's Manufacturer and User Facility Device Experience (MAUDE) database in connection with CAPA 7211 identified only three medical device reports (MDRs) associated with potential foam degradation involving Trilogy ventilators between January 2011 and January 2021. Yet an MOR analysis conducted by Philips in 2018 had already identified 17 documented complaints related to foam degradation in Trilogy ventilators, and at least 14 of those 17 complaints had related MDRs. Similarly, Philips' analysis of foam degradation-related complaints conducted in connection with CAPA 7211 identified 1,254 complaints confirmed to be related to foam degradation between 2014 and April 2021 across all affected products, yet this analysis failed to include several complaints confirmed to be related to foam degradation in Trilogy ventilators that were documented in 2018 in connection with **CAPA INV 0988.**[23]

66. Philips continued to test the PE-PUR Foam while the CAPA was underway. A Biological Risk Assessment dated July 2, 2020, found that "the biological and toxicological risks from exposure to degraded PE-PUR Foam are of concern. . . ."[24]

67. Another internal "Biological Risk Assessment" dated December 10, 2020 – and "conducted as a result of field reports/complaints regarding degraded sound abatement foam in

[22] 483 Report at 18.
[23] 518(b) Notice at 8-9.
[24] 483 Report at 7; *see also id.* ("Philips Respironics Inc. (PRI) was made aware in May 2019 that four CPAP units were returned to a service center with degraded sound abatement foam.")

various CPAP and ventilator products"[25] – described the risks that degraded polyurethane foam posed to humans in no uncertain terms:

> The cytotoxicity and positive genotoxicity results observed from degraded PE-PUR foam samples **indicate a potential patient risk. Potential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure.** Overall, based on an understanding of the toxicological significance of the foam degradants and the results of the ISO 10993 testing to include mutagenic responses in both a bacterial and mammalian system, **the degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to those patient populations who are exposed to degraded PE-PUR foam.**[26]

68. An additional Philips' Biocompatibility Risk Assessment dated January 11, 2021, concurred that degraded PE-PUR Foam "presents a significant biological risk to patients," and goes on to state that "[p]otential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure."[27]

69. Ultimately, in CAPA 7211, Philips concluded that "the cause of the foam degradation condition is long-term exposure to environmental conditions of high temperature combined with high humidity" and restated that "the cause of degradation was due to chemical breakdown of the foam due to exposure to water caused by long-term exposure to environmental conditions."[28]

70. Based on its investigation, the FDA concluded that Philips' upper management was aware of the foam degradation issues, discussed it at numerous management review meetings, and yet delayed doing anything about it – thereby knowingly placing users of its products such as Sharon at risk of serious injury or death:

> [F]irm management, including management with executive responsibility, were aware of potential foam degradation issues concerning CPAPs, BiPAPs, and Trilogy

[25] *Id.* at 8.
[26] *Id.* at 7-8 (emphasis added).
[27] *Id.* at 8.
[28] 518(b) Notice at 10.

> ventilators since at least 01/31/2020, or earlier, and implemented no further corrective actions until April 2021.
>
> Polyester polyurethane foam degradation issues concerning CPAPs, BiPAPs, and Trilogy Ventilators were discussed at all [redacted] management review meetings, since the 2019 [redacted], dated 01/31/2020 . . . . Additionally, your firm [Philips] became aware of this issue and related field complaints in at least 2015 or earlier.[29]

Until The Recall, Philips Advertised Its Breathing Machines As Safe And Effective

71. At no point prior to April 2021, when Philips first disclosed foam issues to its shareholders, did Philips even hint that there was a dangerous condition in the subject devices. Instead, Philips held itself out as a trusted brand and "global leader in the sleep and respiratory markets."[30] Philips further assures consumers like Sharon that its "sleep therapy systems are designed with the needs of care practitioners and patients in mind," and that its "quality systems reflect [Philips'] commitment to providing enhanced patient comfort," among other things. And it has long advertised its CPAP and BiPAP Machines as "clinically proven" treatment for sleep disorders.[31]

72. Philips boasts that it has the "most prescribed CPAP systems by U.S. sleep physicians."[32] The CPAP and BiPAP machines routinely cost from seven or eight hundred dollars to thousands of dollars per machine, and the ventilators cost more than several thousands of dollars per machine.

In April And May 2021, Philips Launched The DreamStation 2

73. Two months prior to the recall, Philips announced on April 13, 2021, that it was launching the DreamStation 2, a next-generation machine in its DreamStation product family. The DreamStation 2 does not contain PE-PUR Foam.

---

[29] 483 Report at 24.
[30] http://www.respironics.com/product library (last accessed June 16, 2022).
[31] https://www.usa.philips.com/healthcare/solutions/sleep (last accessed June 16, 2022).
[32] *See* https://www.usa.philips.com/healthcare/solutions/sleep/sleep-therapy (last accessed June 16, 2022) (citing 2016 Philips survey).

74. Less than two weeks after its launch of the DreamStation 2, on April 26, 2021, Philips finally announced what it had known for years – that its previous generation DreamStation products including the subject device posed serious health risks to users.[33]

75. Even then, Philips' April 26, 2021 statement to investors did not disclose the full extent of its knowledge about the risks posed by the PE-PUR Foam and attempted to deflect the blame on factors such as ozone cleaners. The FDA later rejected this notion, concluding that "the unreasonable risk associated with the products was not caused by the use of ozone cleaning agents, nor did the use of ozone to clean the products constitute a failure to exercise due care."[34]

76. When Philips finally did issue a recall on June 14, 2021, Philips advised CPAP and BiPAP users such as Sharon to "[d]iscontinue use of [their] device." Unfortunately for Sharon, the catastrophic damage to her lungs was already done.

77. On June 14, 2021, as a result of extensive ongoing review following the announcement on April 26, 2021, Philips issued a recall notification for specific affected devices, including the subject device.[35]

78. In its recall notification, Philips identified examples of potential risks which include exposure to degraded PE-PUR Foam particles and exposure to chemical emissions from the PE-PUR Foam material.

79. Philips reported that, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be

[33] https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-first-quarter-results-2021.html (last accessed June 16, 2022).
[34] 518(b) Notice at 10 (emphasis in original).
[35] On July 22, 2021, the FDA upgraded Philips' recall to its most serious classification, Class I: "A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."

life-threatening or cause permanent impairment or require medical intervention to preclude permanent impairment.

80. According to Philips' recall notice, the PE-PUR Foam used in Recalled Devices puts Recalled Device users at risk of suffering from the following health harms: "Particulate exposure can cause headache, irritation [skin, eye and respiratory tract], inflammation, respiratory issues and possible toxic and carcinogenic effects[;]" whereas the "potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting and possible toxic and carcinogenic effects."

81. At all times material, all Defendants participated in and unreasonably and unjustly profited from the manufacture, distribution and sale of the Recalled Devices and unreasonably put users of the Recalled Devices at risk of developing adverse health effects, including cancer.

The Plaintiffs

82. Sharon brings this action on behalf of herself as a purchaser and user of a recalled Philips' DreamStation Auto Continuous Positive Airway Pressure mechanical ventilator device. As a result of her usage of the subject device for three years, on or about August 11, 2022, Sharon was diagnosed with lung cancer, resulting in the need for a lobectomy.

83. Sharon's husband, Allen, brings a derivative claim for loss of consortium arising from injuries relating to those sustained by his lawful spouse, Sharon Lis.

84. At all times when Sharon used the subject device, she did so in accordance with the guidelines, manual, and instructions for use set forth by Defendants.

85. At all times when Sharon used the subject device, she did so for a purpose for which the subject device was marketed, designed, and intended by Defendants.

86. At all times when Sharon used the subject device, she did so in accordance with the directions and instructions issued by her physician who prescribed the use of the subject device.

87. After and as a result of using the subject device, Sharon has suffered personal injuries including but not limited to lung cancer. These injuries would not have occurred but for the defective nature of the subject device and Defendants' wrongful conduct alleged herein.

88. Sharon's use of the subject device caused, or significantly contributed to, her development and progression of lung cancer, which has permanently and irreparably injured her and damaged her quality of life.

89. By reason of the foregoing, Sharon has had to undergo significant treatment and will be required to undergo significant treatment in the future due to the defective nature of the subject device and/or Defendants' wrongful conduct.

90. As a result of the aforesaid conduct and subject device developed, manufactured, designed, sold, distributed, advertised, and promoted by Defendants, Plaintiff was seriously harmed and injured. As a result of such injuries, Plaintiff has suffered damages for which compensatory damages should be awarded.

91. The running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment and/or omission of critical safety information. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff and her physician, the true risks associated with the subject device created, designed, assembled, manufactured, constructed, produced, tested, packaged, labeled, marketed, advertised, promoted, made, distributed and/or sold by Defendants. Due to Defendants' actions, Plaintiff was unaware and could not have reasonably known, or learned through reasonable diligence, that she had been exposed to the risks and harms set forth and that those risks and harms were the direct and proximate result of Defendants' acts or omissions.

ARTICLE 16 ALLEGATIONS

92. If it is deemed that Article 16 of the CPLR applies to this action, the Plaintiffs assert that this action falls within one or more of the exceptions set forth in CPLR 1602 including, but not limited to, the exception for cases where a person is held liable for causing the claimant's injury by having acted with reckless disregard for the safety of others (CPLR 1602(7)); the exception for any parties found to have acted knowingly or intentionally and in concert to cause the acts or failures upon which liability is based (CPLR 1602(11)); and the exception for persons held liable in a product liability action where the manufacturer of the product is not a party to the action and jurisdiction over the manufacturer could not with due diligence be obtained (CPLR 1602(10)).

AS AND FOR A FIRST CAUSE OF ACTION IN NEGLIGENCE AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

93. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "92" of the Complaint herein with the same force and effect as if fully set forth herein.

94. Defendants had a duty to exercise reasonable care in designing, developing, researching, testing, manufacturing, marketing, supplying, promoting, selling and distributing the subject device.

95. Defendants knew, or should have known, that using the recalled devices, including the subject device, created a significantly increased risk of cancer, among other health harms.

96. Upon information and belief, the negligence of the Defendants, their agents, servants and/or employees, included but was not limited to the following acts and/or omissions: Defendants designed and developed the recalled devices, including the subject device, without thoroughly or adequately testing the devices; Defendants sold the recalled devices, including the subject device, without making proper and sufficient tests to determine the dangers to the users;

Defendants failed to adequately and correctly warn the Plaintiff, the public and the medical community of the cancer risks associated with the recalled devices, including the subject device; Defendants had a continuing duty to warn Plaintiff post-manufacture and sale of the dangers in its subject device; Defendants advertised and recommended the use of the recalled devices, including the subject device, for treatment of sleep apnea and other conditions without sufficient knowledge as to the significance of cancer risks; Defendants failed to exercise reasonable care in designing the recalled devices, including the subject device, in a manner which was dangerous to the users; Defendants negligently manufactured the recalled devices, including the subject device, in a manner which was dangerous to the users; Defendants failed to exercise reasonable care when they collectively decided to conceal information concerning cancer risks.

97. Upon information and belief, additionally, Defendants under-reported, underestimated and downplayed the serious dangers of the recalled devices, including the subject device's association with cancer and other health harms.

98. Upon information and belief, Defendants negligently compared the safety risk and/or dangers of the recalled devices, including the subject device, with other forms of treatment for sleep apnea and similar conditions.

99. Upon information and belief, Defendants also failed to warn Plaintiff and Plaintiff's physician, prior to actively encouraging the sale of the subject device, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early detection of cancer.

100. Upon information and belief, Defendants specifically failed to exercise reasonable care when they failed to accompany the subject device with proper and/or accurate warnings regarding all adverse side effects—namely cancer—associated with the use of the subject device. Once Defendants gained additional information about the Recalled Devices' association with

cancer, they failed to update their warnings and thereafter accompany the Recalled Devices with adequate warnings regarding cancer.

101. Upon information and belief, despite the fact that Defendants knew, or should have known, that the Recalled Devices caused unreasonably dangerous side effects, like cancer, they made conscious decisions to downplay these risks and continue to market, manufacture, distribute and/or sell the devices to physicians and patients, including Plaintiff Sharon Lis.

102. Upon information and belief, Defendants knew, or should have known, that consumers, such as Plaintiff Sharon Lis, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

103. Upon information and belief, Defendants' negligence was the proximate cause of Plaintiff Sharon Lis' injuries, among many other health harms, which Sharon Lis suffered and/or will continue to suffer.

104. As a result of the foregoing acts and omissions, Plaintiff Sharon Lis was caused to suffer serious and dangerous side effects that led to serious and permanent personal injuries, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications and fear of redeveloping cancer.

105. As a direct and proximate result of the Defendants' negligence, Plaintiff Sharon Lis suffered and will continue to suffer damages for which she is entitled to recovery.

106. Upon further information and belief, Defendants' conduct described herein consisted of misrepresentation, oppression, fraud and/or malice and was done with advance knowledge, conscious disregard of the safety of others and/or ratification by Defendants' officers, directors and/or managing agents.

107. Upon information and belief, despite their knowledge of the Recalled Devices' propensity to cause cancer and other serious injuries, Defendants chose profits over the safety of American citizens suffering with sleep apnea when they sought to create and market a device posing significant health risks.

108. Upon information and belief, despite having substantial information about the Recalled Devices' serious and unreasonable side effects, Defendants intentionally and recklessly failed to adequately warn the public, physicians and the medical community.

109. Upon information and belief, despite having substantial information about the Recalled Devices' serious and unreasonable side effects, Defendants failed to make the decision to pull the devices from the market after receiving indications and after receiving reports from consumers who were experiencing serious injuries associated with the use of the devices.

110. Upon information and belief, Defendants downplayed and recklessly disregarded their knowledge of the defective nature of the Recalled Devices' potential for causing serious injuries.

111. Upon information and belief, Defendants chose to do nothing to warn the public about the serious and undisclosed side effects with the Recalled Devices.

112. Upon information and belief, Defendants recklessly failed to warn and adequately instruct physicians, including Plaintiff Sharon Lis' physician, regarding the increase in reports from consumers who were experiencing serious injuries associated with the use of the Recalled Devices.

113. As a result of the negligence of the Defendants, the Plaintiff has been injured and is claiming damages in an amount exceeding the jurisdictional limits of all other courts which would otherwise have jurisdiction over this matter.

114. The intentional and willful conduct above complained of against the Defendants was aimed against the public as well as the Plaintiff; was grossly unjust and involved high moral culpability for which punitive damages should be assessed in a sum of money to be determined by the trier of fact.

AS AND FOR A SECOND CAUSE OF ACTION IN STRICT PRODUCTS LIABILITY – DESIGN DEFECT, AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

115. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "114" of the Complaint herein with the same force and effect as if fully set forth herein.

116. Upon information and belief, at all times herein mentioned, Defendants were involved in the business of researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices, including the subject device, which are defective and unreasonably dangerous.

117. Upon information and belief, the subject device was originally designed, sold and distributed by Defendants.

118. Upon information and belief, the design of the Recalled Device (including the subject device) and use of the PE-PUR Foam and the placement of the foam within the Recalled Devices, were defective and unreasonably dangerous, causing degradation and inhalation of the PE-PUR Foam and causing headaches, irritation, inflammation, respiratory issues and exposure to materials with toxic and carcinogenic effects.

119. Upon information and belief, the design of the Recalled Devices, including the subject device, and the PE-PUR Foam rendered devices, were not reasonably fit, suitable or safe for their intended purpose.

120. Upon information and belief, the Recalled Devices, including the subject device, did not perform as an ordinary consumer would expect.

121. Upon information and belief, at the time the Recalled Devices, including the subject device, were designed, manufactured, sold and distributed by Defendants, they were defective in design and unreasonably dangerous as designed.

122. Upon information and belief, at the time the subject device was sold, the defective design caused the product to unexpectedly fail to function in a manner reasonably expected by an ordinary consumer and user of such device. The defective and unreasonably dangerous design of the device was a proximate cause of the injuries and damages to the Plaintiff.

123. Upon information and belief, the dangers of the Recalled Devices, including the subject device, outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are other CPAP machines that do not use a similarly toxic foam that is subject to degradation, inhalation and ingestion.

124. Upon information and belief, safer alternative machines from other manufacturers were available that did not suffer from the defect as set forth herein and that did not have an unreasonable risk of harm as with the Recalled Devices, including the subject device, and their unsafe PE-PUR Foam.

125. Upon information and belief, the risk benefit profile of the Recalled Devices, including the subject device, was unreasonable and the Recalled Devices, including the subject device, should have had stronger and clearer warnings or should not have been sold in the market.

126. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable diligence, the defective nature of the subject device. Further, in no way could Plaintiff have known that Defendants had designed, developed, manufactured and distributed the subject device in a way as to make the risk of harm or injury outweigh any benefits.

127. The subject device was expected to and did reach Plaintiff Sharon Lis without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

128. At the time of the incident, the product was in substantially the same condition as it was at the time it was placed into the stream of commerce. No material alterations were made to the product. At the time of the incident, the product was in the same or substantially similar condition as when it left the control of Defendants.

129. The subject device was used for its intended purposes by Plaintiff Sharon Lis and the subject device was not materially altered or modified prior to its use.

130. Plaintiff Sharon Lis purchased the subject device on April 11, 2018.

131. Plaintiff Sharon Lis used the subject device regularly to treat a health condition until learning that the device was recalled on or about June 14, 2021.

132. Plaintiff Sharon Lis used the subject device in a foreseeable manner. Nonetheless, the use of the subject device was unreasonably dangerous and caused serious harm and injuries to Plaintiff.

133. The subject device was being used in a way which the Defendants intended at the time it was prescribed to Plaintiff Sharon Lis.

134. Defendants had a duty to create a device that was not unreasonably dangerous for its normal, intended use and breached this duty.

135. Upon information and belief, Defendants knew, or should have known, that the Recalled Devices, including the subject device, would be prescribed to patients and that physicians and patients were relying on them to furnish a suitable device. Further, Defendants knew, or should have known, that patients by whom the Recalled Devices would be used, such as Sharon Lis, could be and would be affected by the defective design and composition of the devices.

136. Upon information and belief, Defendants researched, designed, manufactured, tested, advertised, promoted, marketed and distributed a defective device which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiff Sharon Lis and her husband (loss of consortium), and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

137. As a direct and proximate result of Defendants' placement of the subject defective device into the stream of commerce and Plaintiff Sharon Lis' use of the product as designed, manufactured, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff Sharon Lis suffered serious physical and mental injuries including but not limited to lung cancer, debilitating injuries, harm, damages and economic loss and will continue to suffer great pain, discomfort, harm, damages and economic loss in the future as a result of being unable to attend to her ordinary affairs and she is and will remain disfigured.

138. That by reason of the foregoing, the Defendants are liable to Plaintiffs under New York's Strict Products Liability in the amount set forth in Paragraphs "113" and "114" of this Complaint.

139. That by reason of the foregoing on the part of the Defendants, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

AS AND FOR A THIRD CAUSE OF ACTION IN STRICT PRODUCTS LIABILITY – FAILURE TO WARN AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

140. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "139" of the Complaint herein with the same force and effect as if fully set forth herein.

141. Defendants had a duty to warn Plaintiff Sharon Lis regarding the defect and true risks associated with the Recalled Devices, including the subject device.

142. Upon information and belief, Defendants are liable under the theory of strict products liability. Defendants were, at all times relevant to this suit, engaged in the business of designing, manufacturing, testing, marketing, distributing and placing into the stream of commerce CPAP and BiPAP devices for sale to and for use by members of the public, including the subject device at issue in this lawsuit.

143. The subject device manufactured by Defendants reached Plaintiff Sharon Lis without substantial change and was used as directed. Upon information and belief, the subject device used by Plaintiff Sharon Lis was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Plaintiff Sharon Lis.

144. Defendants, as manufacturers of CPAP and BiPAP devices, are held to the level of knowledge of an expert in the field. Further, Defendants knew, or should have known, that warnings and other relevant information and data which they distributed regarding the defect of the device and associated health risks with the use of devices were inadequate.

145. Upon information and belief, at all times herein mentioned, Defendants designed, developed, researched, tested and knew, or should have known, about the significant cancer risks of the subject device.

146. At all times herein mentioned, Defendants advertised, promoted, marketed, sold and distributed the subject device that was used by Plaintiff Sharon Lis.

147. The subject device was expected to and did reach the usual consumers, handlers and persons coming into contact with said device without substantial change in the condition in which it was produced, manufactured, sold, distributed and marketed by the Defendants.

148. Defendants each had an independent duty and a continuing duty to warn the medical community and consumers, including Plaintiff Sharon Lis and her physician, about the significance of the risks of cancer and other health harms associated with the subject device as it became or could have become available to Defendants.

149. Plaintiff Sharon Lis used the subject device in a manner intended and foreseeable by Defendants.

150. Upon information and belief, the subject device was defective due to inadequate warnings because Defendants knew, or should have known, that the product created a significantly increased risk of cancer, among other health impacts, and failed to warn the medical community and Plaintiff's physician of the nature of such risks.

151. Defendants failed to provide adequate warnings regarding the risks of the PE-PUR Foam.

152. Upon information and belief, Defendants omitted and downplayed the significantly increased risks of cancer and other health risks associated with the Recalled Devices, including the subject device, that Defendants knew, or should have known, from previous testing and research even prior to subject device's FDA approval.

153. Upon information and belief, Defendants falsely represented to Plaintiff Sharon Lis and her physician that the subject device was safe for human use.

154. Upon information and belief, despite Defendants' obligation to unilaterally strengthen the warnings, Defendants instead chose to actively conceal this knowledge.

155. Upon information and belief, Defendants intentionally, knowingly and recklessly made these misrepresentations to induce Plaintiff's prescribing physician to prescribe and Plaintiff Sharon Lis to purchase, the Recalled subject device.

156. Plaintiff Sharon Lis and her prescribing physician did not have the same knowledge as Defendants and no adequate warning or other relevant information and data was communicated to Plaintiff Sharon Lis or her physician.

157. Among other defects, the subject device's labeling and warnings were defective because they omitted and inadequately warned of the device's risk of cancer and other health risks.

158. Upon information and belief, Defendants had information regarding the true risks but failed to warn Plaintiff Sharon Lis and her prescribing physician about the true risks stated herein and Defendants chose not to strengthen their warnings.

159. Although physicians are supposed to weigh the risks and benefits before prescribing a medical device, upon information and belief, Defendants knew that their deliberate omissions would cause physicians, including Plaintiff Sharon Lis' physician, to prescribe the subject device without being able to adequately weigh the risk of device's risk of cancer and other health risks.

160. If Defendants would have properly warned about the subject device's cancer risk and/or other health harms, Plaintiff Sharon Lis' prescribing physician would not have recommended or prescribed the subject device and Plaintiff Sharon Lis would not have purchased or used the subject device because the potential benefits of the subject device are significantly outweighed by the risk of cancer and other harms.

161. Had Defendants reasonably provided adequate warnings of cancer, such warnings would have been heeded and no healthcare professional, including Plaintiff Sharon Lis' physician, would have prescribed the subject device and no consumer, including Plaintiff Sharon Lis, would have purchased and/or used the subject device. Instead, Plaintiff's prescribing physician would have prescribed and Plaintiff Sharon Lis would have purchased and used a safer alternative device or recommended and used an alternative course of medical treatment that did not include the subject device.

162. Defendants had an obligation to provide Plaintiff Sharon Lis and Sharon Lis' physician with adequate information, data and warnings regarding the risks associated with the use of the subject device and/or that there existed safer and more or equally effective alternative devices.

163. Upon information and belief, Defendants knew that their representations to plaintiff about the Recalled Devices, including the subject device, were false in that the Recalled Devices, including the subject device, contained PE-PUR Foam that placed users like plaintiff at risk of adverse health effects from the continued inhalation of the Recalled Devices, including the subject device, which does not conform to the products' labels, packaging, advertising and statements.

164. Upon information and belief, Defendants knowingly allowed their packaging, labels, advertisements, promotional materials and websites to intentionally mislead consumers, such as Plaintiff Sharon Lis, and Plaintiff's prescribing physician.

165. Defendants marketed, promoted, distributed and sold the unreasonably dangerous and defective Recalled Devices, including the subject device, to consumers, Plaintiff Sharon Lis, and her prescribing physician without adequate warnings and other relevant information and data. Upon information and belief, through both omission and affirmative misstatements, Defendants misled Plaintiff Sharon Lis and her prescribing physician about the health risks associated with the use of the Recalled Devices, including the subject device, which resulted in injury to Plaintiff.

166. Plaintiff Sharon Lis would not have purchased, chosen, used and/or paid for all or part of the subject device and Plaintiff's prescribing physician would not have prescribed the subject device if they had known of the defect and the risks of purchasing and using the device.

167. Plaintiff Sharon Lis and Plaintiff's prescribing physician did in fact rely on these misrepresentations and omissions and Plaintiff Sharon Lis was prescribed and she purchased and used the subject device as a result of those misrepresentations and omissions. Given the deceptive

manner in which Defendants advertised, represented and otherwise promoted the Recalled Devices, including the subject device, Plaintiff's and Plaintiff's physician's reliance on Defendants' misrepresentations was justifiable.

168. By failing to provide Plaintiff Sharon Lis and her physician with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with use of the Recalled Devices, including the subject device, and/or that there existed safer and more equally effective alternative devices, Defendants breached their duty of reasonable care and safety.

169. Upon information and belief, Defendants' actions described above were performed willfully, intentionally and with reckless disregard of the life and safety of Plaintiff Sharon Lis and the public.

170. As a direct and proximate result of the subject device's defects as described herein that was placed into the stream of commerce, Plaintiff Sharon Lis developed cancer, suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has further suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost her ability to live a normal life and will continue to be so diminished in the future.

171. By reason of the foregoing, the Defendants are liable to the plaintiffs under New York Strict Products Liability in an amount set forth in Paragraphs "113" and "114" of this Complaint.

AS AND FOR A FOURTH CAUSE OF ACTION IN STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

172. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "171" of the Complaint herein with the same force and effect as if fully set forth herein.

173. Defendants are liable under the theory of strict products liability. Defendants were at all times relevant to this suit and are now engaged in the business of researching, designing, manufacturing, testing, marketing, selling, disturbing and/or placing into the stream of commerce the Recalled Devices, including the subject device, which are defective and unreasonably dangerous.

174. The subject device was expected to and did reach Plaintiff Sharon Lis without a substantial change in its condition.

175. Upon information and belief, the finished subject device deviated, in terms of construction and quality, from the specifications or planned output in a manner that made it unreasonably dangerous.

176. Upon information and belief, at all relevant times, the Recalled Devices, including the subject device, were defectively and improperly manufactured and designed by Defendants in that Defendants continued to supply consumers with the Recalled Devices despite having full knowledge that the devices posed substantial and avoidable bodily injury.

177. Upon information and belief, the foreseeable risks of the subject device were known to Defendants and could have been avoided.

178. Upon information and belief, at all relevant times, the subject device was defectively manufactured by Defendants in that its design and formulation is more dangerous than what an ordinary consumer would expect when used in an intended and reasonably foreseeable manner.

179. Upon information and belief, at all relevant times, Defendants actively deceived users that their use of the Recalled Devices posed safety risks that far outweighed any benefits.

180. Upon information and belief, the Recalled Devices, including the subject device, were defectively manufactured in that the PE-PUR Foam comprising part of the devices can

degrade into particles that enter the devices' air pathway and can off-gas certain chemicals. These characteristics cause, among other problems, cancer. Plaintiff Sharon Lis and other similarly situated consumers were unknowingly subjected to receiving different doses of toxins, carcinogens and other deleterious components and contaminants when using the Recalled Devices.

181. As a direct and proximate result of the defective manufacture of the subject device placed into the stream of commerce, Plaintiff Sharon Lis suffered and will continue to suffer damages for which she is entitled to recovery.

182. By reason of the foregoing, the Defendants are liable to the Plaintiff in an amount set forth in Paragraphs numbered "113" and "114" of this Complaint.

AS AND FOR A FIFTH CAUSE OF ACTION IN FRAUD AND MISREPRESENTATION AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

183. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "182" of the Complaint herein with the same force and effect as if fully set forth herein.

184. Upon information and belief, an inspection of Philips' internal company records conducted by the Food and Drug Administration (hereinafter "FDA") during August through November, 2021 reflects the following:

- As early as 2015, Philips was made aware that the polyester polyurethane foam in its devices was degrading during normal use;
- In 2016, Philips learned that the polyester polyurethane foam in its machines could degrade and break down in as little as one year of use;
- Records of users of Philips' devices reflect that since 2008, Philips received notice of over 222,000 complaints of degradation of the polyester polyurethane foam across all Philips' products containing the affected foam;

- By 2019, Philips was aware that biological risk assessments conducted in the field in response to reports/complaints regarding degraded and broken down polyester polyurethane foam in various CPAP products indicated the potential for cancer and other biological and toxicological risks from exposure to the degraded polyester polyurethane foam;
- As early as 2020, internal company documents revealed that the subject device failed emissions testing, exceeding tolerable limits, for the release of volatile organic compounds due to the foam's degrading.

185. As set forth above in Plaintiffs' "Factual Allegations", upon information and belief, Plaintiffs allege that Philips made affirmative misrepresentations regarding the safety and effectiveness of the subject device and omitted and withheld material safety information regarding the subject device to Plaintiff and her prescribing physician. Upon information and belief, among other wrongful conduct identified above, Philips fraudulently misrepresented the safety of its subject devices and failed to inform users and/or the medical profession that these devices containing polyester based polyurethane were breaking down into toxic particles that could be inhaled by users of these breathing machines.

186. Upon information and belief, plaintiff further alleges that during this period of time, while knowing that its polyester foam insulation devices were breaking down and releasing toxic particles that could be breathed in by the user, Philips failed to warn and continued to fraudulently misrepresent the safety of its products to users and the medical profession all to the detriment of plaintiff and others similarly situated.

187. Defendants had a duty to exercise reasonable care to those to whom they provided device information about the Recalled Devices and to all those relying on the information

provided, including Plaintiff Sharon Lis, her healthcare providers and the public in general that the devices had been tested and found to be safe and effective for treating sleep apnea.

188. Upon information and belief, Defendants, in the course of selling the Recalled Devices, supplied information about the devices through television commercials, advertisements, marketing campaigns, sales representatives, labeling and warnings.

189. Defendants breached their duty by misrepresenting the subject device's safety to the medical and healthcare community, to Plaintiff Sharon Lis and Plaintiff's prescribing physician.

190. Defendants failed to exercise reasonable care because their goal should have been to put safety before their profits by providing individuals with the realistic risks and expectations that the Recalled Devices could cause cancer and other serious injuries.

191. Defendants' representations were made without properly conducting sufficient testing and by providing insufficient warnings about the Recalled Devices' potential risks.

192. Defendants' false representations that the Recalled Devices were safe for consumers and their failure to disclose material past and existing facts of the Recalled Devices' risk of cancer were made or omitted with the intent to induce Plaintiff Sharon Lis and her prescribing physician to rely upon those facts or omissions.

193. Plaintiff Sharon Lis and her physician were unaware and did not know that the subject device was unsafe for the purpose of treating sleep apnea because it caused a significant increased risk of cancer until after she had been exposed to carcinogenic particles and gasses.

194. Plaintiff Sharon Lis and her physician justifiably relied upon the false representations and omissions of Defendants.

195. Had Defendants provided adequate warnings of cancer and other serious injuries, such warnings would have been heeded by plaintiff and her prescribing physician.

196. Had Defendants reasonably provided adequate warnings of cancer, such warnings would have been heeded and no healthcare professional, including Plaintiff Sharon Lis' physician, would have prescribed the subject device and no consumer, including Plaintiff Sharon Lis, would have purchased and/or used the subject device. Instead, Plaintiff's prescribing physician would have prescribed and Plaintiff Sharon Lis would have purchased and used a safer alternative device or recommended and used an alternative course of medical treatment that did not include the subject device.

197. As a direct and proximate result of the foregoing acts and omissions, Plaintiff Sharon Lis was caused to suffer serious and dangerous side effects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications and fear of redeveloping cancer and is entitled to an amount of damages as set forth in Paragraphs "113" and "114" of this Complaint. Plaintiffs do not allege a claim or cause of action for fraud on the FDA.

AS AND FOR A SIXTH CAUSE OF ACTION IN BREACH OF EXPRESS WARRANTY AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

198. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "197" of the Complaint herein with the same force and effect as if fully set forth herein.

199. At all relevant times, Defendants, through their advertising and promotional materials, expressly and impliedly warranted and affirmed that the subject devices' purpose was to offer a reasonably safe treatment for sleep apnea and similar health problems.

200. Upon information and belief, Defendants touted the subject devices as safe, despite knowingly having never adequately researched or tested the devices to assess their safety before placing the devices on the market and promoting them to consumers.

201. Defendants intended to make Plaintiff Sharon Lis and the general public believe the subject devices were safe.

202. Upon information and belief, Defendants knowingly mislead Plaintiff Sharon Lis and the general public to believe the subject devices were safe for use, despite knowing that the devices could lead to serious injuries, all of which Defendants knew, or by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff Sharon Lis would be victim to.

203. Upon information and belief, at all relevant times, Defendants had knowledge of the hazards and health risks posed by the Recalled Devices when used.

204. Upon information and belief, at all relevant times, Defendants willfully failed to disclose the defects and health risks of the Recalled Devices to Plaintiff Sharon Lis and the consuming public.

205. Plaintiff Sharon Lis relied, to her detriment, on the information publicized by Defendants.

206. In reliance upon these warranties as to the safety of the subject device by Defendants, Plaintiff Sharon Lis acquired/purchased and used the subject device, believing that the subject device was inherently safe.

207. Plaintiff Sharon Lis notified Defendants of the breach.

208. As a direct and proximate result of the foregoing acts and omissions, Plaintiff Sharon Lis suffered and will continue to suffer damages in an amount as set forth in Paragraphs "113" and "114" for which she is entitled to recovery.

AS AND FOR A SEVENTH CAUSE OF ACTION UNDER IMPLIED WARRANTY OF MERCHANTABILITY AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

209. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "208" of the Complaint herein with the same force and effect as if fully set forth herein.

210. Upon information and belief, at all relevant times, Defendants have been merchants in regard to the recalled devices, including the subject device, they created and sold to consumers.

211. Upon information and belief, Defendants breached their implied warranty of merchantability since the subject devices were defective when created and designed and do not conform with the promises represented on their labels.

212. Upon information and belief, Defendants failed to comply with merchantability requirements, as the subject devices do not achieve the ordinary purposes they advertise: a healthy treatment for respiratory conditions such as sleep apnea.

213. Beyond Defendants' own direct sales of the subject devices, Plaintiff Sharon Lis and other consumers are third-party beneficiaries of Defendants' agreements with their distributors, dealers and sellers for the distribution, dealing and sale of the Recalled Devices to consumers. Plaintiff Sharon Lis and consumers are the intended beneficiaries of Defendants' implied warranties since the Recalled Devices are manufactured with the express and intended purpose of selling the devices to consumers.

214. As a direct and proximate result of Defendants' breach of their implied warranties of merchantability regarding the subject device, Plaintiff Sharon Lis was damaged because, had she been aware of the unmerchantable condition of the subject device, she would have not acquired/purchased/used the subject device and not suffered injuries and damages from its use.

215. As a direct and proximate result of the foregoing acts and omissions, Plaintiff Sharon Lis suffered and will continue to suffer damages in an amount as set forth in Paragraphs "113" and "114" for which she is entitled to recovery.

AS AND FOR AN EIGHTH CAUSE OF ACTION UNDER LOSS OF CONSORTIUM AGAINST THE NAMED DEFENDANTS, PLAINTIFF ALLEN LIS ALLEGES:

216. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "215" of the Complaint herein with the same force and effect as if fully set forth herein.

217. At all relevant times, Plaintiff Allen Lis was and still is the lawful spouse of Plaintiff Sharon Lis and as such was entitled to her services.

218. At all relevant times, Plaintiff Allen Lis has been deprived of the services, society, companionship, consortium and support of his wife, Plaintiff Sharon Lis, all to his damage.

219. That by reason of the foregoing, Plaintiff Sharon Lis was compelled to seek and obtain medical aid and attention and Plaintiff Allen Lis did necessarily pay and become liable therefor, for medicines and medical care and upon information and belief, Plaintiff Sharon Lis will necessarily incur further similar expenses.

220. That by reason of the foregoing, Plaintiff Allen Lis has been damaged in an amount that exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

WHEREFORE, Plaintiffs demand judgment against the Defendants in the First, Second, Third, Fourth, Fifth, Sixth, Seventh and Eighth Causes of Action in an amount exceeding the jurisdictional limits of all other courts which would otherwise have jurisdiction over this matter; punitive damages in a sum of money to be determined by the trier of fact; and for such other and further relief as may be just and proper, together with the costs and disbursements of this action.

DEMAND FOR JURY TRIAL

221. Plaintiffs demand a jury trial on all counts in this Verified Complaint.

Dated this 10th day of August, 2023.

Michael A. Ponterio, Esq.
Lipsitz, Ponterio & Comerford LLC
424 Main Street, Suite 1500
Buffalo, NY 14202
Phone: (716) 849-0701
Fax: (716) 849-0708

Connor G. Sheehan, Esq.*
Texas Bar No. 24046827
csheehan@dunnsheehan.com
DUNN SHEEHAN LLP
5910 N. Central Expressway, Suite 1310
Dallas, Texas 75206
Phone: (214) 866-0077
Fax: (214) 866-0070
**pro hac vice application forthcoming*

Attorneys for Plaintiffs

VERIFICATION

STATE OF NEW YORK)
COUNTY OF ERIE) SS.:
CITY OF BUFFALO)

The undersigned, an attorney admitted to practice in the courts of the State of New York, shows: that deponent is a member of the firm of LIPSITZ, PONTERIO & COMERFORD LLC, the attorneys of record for the plaintiffs in the within action; that deponent has read the foregoing Verified Complaint and knows the contents thereof; that the same is true to deponent's own knowledge, except as to those matters therein stated to be alleged upon information and belief and as to those matters deponent believes it to be true. Deponent further says that the reason this verification is made by deponent and not by plaintiffs, SHARON LIS and ALLEN LIS, is because said plaintiffs are not in Erie County which is the county where deponent has his principal office.

The grounds of deponent's belief as to all matters not stated upon deponent's knowledge are as follows: records, reports and correspondence in deponent's file.

The undersigned affirms that the foregoing statements are true, under the penalties of perjury.

Dated: August 10, 2023

Michael A. Ponterio

MICHAEL A. PONTERIO, ESQ.

EXHIBIT D

Notice of Service of Process

null / ALL
Transmittal Number: 27487551
Date Processed: 08/17/2023

Primary Contact:
Barbara Bickford
Philips North America LLC
222 Jacobs St
Fl 3
Cambridge, MA 02141-2289

Entity:	Philips Holding USA Inc. Entity ID Number 1920728
Entity Served:	Philips Holding USA, Inc
Title of Action:	Sharon Lis vs. Koninklijke Philips N.V.
Matter Name/ID:	Sharon Lis vs. Koninklijke Philips N.V. (14485630)
Document(s) Type:	Summons/Complaint
Nature of Action:	Product Liability
Court/Agency:	Niagara County Supreme Court, NY
Case/Reference No:	E180656/2023
Jurisdiction Served:	Delaware
Date Served on CSC:	08/17/2023
Answer or Appearance Due:	30 Days
Originally Served On:	CSC
How Served:	Personal Service
Sender Information:	Lipsitz, Ponterio & Comerford LLC 716-849-0701

Information contained on this transmittal form is for record keeping, notification and forwarding the attached document(s). It does not constitute a legal opinion. The recipient is responsible for interpreting the documents and taking appropriate action.

To avoid potential delay, please do not send your response to CSC

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NIAGARA

----------x

SHARON LIS and
ALLEN LIS, her spouse

Plaintiff/Petitioner,

- against -

Index No. E180656/2023

KONINKLIJKE PHILIPS N.V., et al.

Defendant/Respondent.

----------x

NOTICE OF ELECTRONIC FILING
(Consensual Case)
(Uniform Rule § 202.5-b)

You have received this Notice because:

1) The Plaintiff/Petitioner, whose name is listed above, has filed this case using the New York State Courts E-filing system ("NYSCEF"), and

2) You are a Defendant/Respondent (a party) in this case.

- **If you are represented by an attorney:**
  Give this Notice to your attorney. (Attorneys: see "Information for Attorneys" pg. 2).

- **If you are not represented by an attorney:**
  You will be served with all documents in paper and you must serve and file your documents in paper, unless you choose to participate in e-filing.

  If you choose to participate in e-filing, you must have access to a computer and a scanner or other device to convert documents into electronic format, a connection to the internet, and an e-mail address to receive service of documents.

  The **benefits of participating in e-filing** include:

  - serving and filing your documents electronically
  - free access to view and print your e-filed documents
  - limiting your number of trips to the courthouse
  - paying any court fees on-line (credit card needed)

  To register for e-filing or for more information about how e-filing works:

  - visit: www.nycourts.gov/efile-unrepresented or
  - contact the Clerk's Office or Help Center at the court where the case was filed. Court contact information can be found at www.nycourts.gov

To find legal information to help you represent yourself visit www.nycourthelp.gov

Information for Attorneys

An attorney representing a party who is served with this notice must either consent or decline consent to electronic filing and service through NYSCEF for this case.

Attorneys registered with NYSCEF may record their consent electronically in the manner provided at the NYSCEF site. Attorneys not registered with NYSCEF but intending to participate in e-filing must first create a NYSCEF account and obtain a user ID and password prior to recording their consent by going to www.nycourts.gov/efile

Attorneys declining to consent must file with the court and serve on all parties of record a declination of consent.

For additional information about electronic filing and to create a NYSCEF account, visit the NYSCEF website at www.nycourts.gov/efile or contact the NYSCEF Resource Center (phone: 646-386-3033; e-mail: nyscef@nycourts.gov).

Dated: August 10, 2023

Michael A. Ponterio, Esq.
Name

LIPSITZ, PONTERIO & COMERFORD, LLC
Firm Name

424 Main Street, Suite 1500

Buffalo, New York 14202
Address

(716) 849-0701
Phone

map@lipsitzponterio.com
E-Mail

TO: ALL NAMED DEFENDANTS

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NIAGARA

SHARON LIS and
ALLEN LIS, her spouse
5384 County Road 36
Honeoye, NY 14471

Plaintiffs,

vs.

KONINKLIJKE PHILIPS N.V.
Philips Center
Amstelplein 2,
1096 BC Amsterdam
The Netherlands

PHILIPS NORTH AMERICA LLC
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

PHILIPS RS NORTH AMERICA LLC
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

PHILIPS HOLDING USA, INC.
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

PHILIPS HEALTHCARE
222 Jacobs Street
Cambridge, MA 02141

HEALTH SYSTEM SERVICES, LTD.
6867 Williams Road
Niagara Falls, NY 14304

Defendants.

SUMMONS

Plaintiffs designate Niagara County as the place of trial

The basis of venue is the residence of a defendant

Defendant, Health System Services, Ltd., resides at 6867 Williams Road Niagara Falls, NY

County of Niagara

TO THE ABOVE-NAMED DEFENDANTS:

YOU ARE HEREBY SUMMONED to answer the Verified Complaint in this action and to serve a copy of your answer, or, if the Verified Complaint is not served with this Summons, to

serve a notice of appearance on the Plaintiffs' Attorneys within 20 days after the service of this Summons, exclusive of the day of service (or within 30 days after the service is complete if this Summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the Verified Complaint.

Dated: Buffalo, New York
August 10, 2023

Michael A. Ponterio, Esq.
Lipsitz, Ponterio & Comerford, LLC
424 Main Street, Suite 1500
Buffalo, NY 14202
Phone: 716.849.0701
Fax: 716.849.0708

Connor G. Sheehan*
Texas Bar No. 24046827
csheehan@dunnsheehan.com
DUNN SHEEHAN LLP
5910 N. Central Expressway, Suite 1310
Dallas, Texas 75206
Phone: 214.866.0077
Fax: 214.866.0070
**pro hac vice application forthcoming*

Attorneys for Plaintiffs

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NIAGARA

SHARON LIS and
ALLEN LIS, her spouse,

Plaintiffs,

VERIFIED COMPLAINT

vs.

KONINKLIJKE PHILIPS N.V.,
PHILIPS NORTH AMERICA LLC,
PHILIPS RS NORTH AMERICA LLC,
PHILIPS HOLDING USA, INC.,
PHILIPS HEALTHCARE,
HEALTH SYSTEM SERVICES, LTD.,

Defendants.

Plaintiffs SHARON LIS and ALLEN LIS ("Plaintiffs"), by and through their counsel, file this Verified Complaint against Defendants KONINKLIJKE PHILIPS N.V. ("Royal Philips"), PHILIPS NORTH AMERICA LLC ("Philips NA"), PHILIPS RS NORTH AMERICA LLC ("Philips RS"), PHILIPS HOLDING USA, Inc. ("PHUSA"), PHILIPS HEALTHCARE ("PHC" and, collectively with Royal Philips, Philips NA, Philips RS, and PHUSA, "Philips"), and HEALTH SYSTEM SERVICES, LTD. ("HSS" and, collectively with Philips, "Defendants").

INTRODUCTION

1. Plaintiff Sharon Lis ("Sharon") brings this action on behalf of herself for personal injuries that she sustained as a purchaser and long-time user of a defective Philips DreamStation Auto Continuous Positive Airway Pressure mechanical ventilator device (the "DreamStation CPAP machine" or "subject device") that contains polyester-based polyurethane sound abatement foam ("PE-PUR Foam"). On June 14, 2021, Phillips recalled the DreamStation CPAP machine due to the PE-PUR Foam's known propensity to break down, resulting in small pieces of foam and invisible chemicals being breathed in or swallowed by the user resulting in serious and permanent

injuries. Plaintiff Allen Lis ("Allen") brings a derivative claim for loss of consortium arising from injuries relating to those sustained by his lawful spouse, Sharon.

2. Philips develops, manufactures, markets, imports, sells, and distributes a variety of products for sleep and home respiratory care. Philips also develops, manufactures, markets, imports, sells, and distributes a variety of ventilator devices for patients with respiratory conditions.

3. On April 26, 2021, Philips publicly announced its determination that there were risks that the PE-PUR Foam used in certain CPAP, Bi-Level PAP, and mechanical ventilator devices manufactured by Philips – specifically including the subject device used by Sharon – will degrade or off-gas under certain circumstances.

4. On June 14, 2021, Royal Philips issued a recall ("Recall Notice") in the United States of its CPAP, Bi-Level PAP, and mechanical ventilator devices containing PE-PUR Foam – specifically including the subject device. In particular, Philips disclosed for the first time its determination that (a) the PE-PUR Foam in those devices emits volatile organic compounds which, when inhaled, can result in serious adverse health effects, including but not limited to acute respiratory distress syndrome (ARDS), lung disease, lung damage, chemical poisoning, heart attack, heart failure, kidney disease, reactive airway disease (RAD), respiratory failure, severe inflammation, and multiple types of cancer.

5. In total, Philips announced that "between 3 million and 4 million" devices were targeted in the recall. In its Recall Notice, Philips advised of serious health risks related to the PE-PUR Foam and recommended that patients using the recalled CPAP and Bi-Level PAP devices immediately discontinue use of the devices and consult with their physicians regarding alternative ventilator options.

6. On or about April 11, 2018 – more than three years before Philips issued the Recall Notice – the subject device used by Plaintiff Sharon Lis was distributed by HSS. This device, the Philips' subsequently-recalled devices, the DreamStation CPAP Machine, Serial No. J2125235256ED, was used by Plaintiff Sharon Lis to treat her obstructive sleep apnea. Sharon, a 55-year-old lifetime nonsmoker, used the CPAP device on a regular basis from the date she acquired it in early 2018 until approximately June 2021.

7. On or about August 11, 2022, as a result of her extended usage of the subject device, Sharon was diagnosed with bronchogenic carcinoma, a cancerous tumor originating in her lung along the right middle portion of her chest that can only be removed surgically. On or about November 2, 2022, Sharon underwent a right middle lobectomy to remove a section of the carcinoid tumor in her lung. The surgery resulted in only half of the cancerous tumor being removed due to its location on her lung.

8. As a direct and proximate result of her long-term use of Defendants' defective and dangerous device, Sharon has suffered and continues to suffer from severe symptoms of lung cancer, requiring continuous medical treatments and resulting in severe associated pain, suffering, and emotional distress.

9. Among other things, Sharon must have frequent scans of her body and blood work to determine if the cancer has grown or spread, which will result in a second surgery to remove the remainder of her cancerous lung. She is prescribed several pain medications to be able to tolerate the extreme pain that this cancer causes.

10. As a direct and proximate result of Defendants' wrongful conduct alleged herein, Sharon has suffered, continues to suffer, and will for the foreseeable future suffer from serious and dangerous side effects as a result of the cancer, as well as other severe and personal injuries which

are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and requires lifelong medical treatment and monitoring.

PARTIES

11. Plaintiffs are citizens of the State of New York, residing in Ontario County. Plaintiff Allen Lis is the lawful wedded spouse of Plaintiff Sharon Lis.

12. Upon information and belief, Defendant Royal Philips is a public limited liability company established under the laws of The Netherlands, having its principal executive offices at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the parent company of Philips North America, LLC and Philips RS North America, LLC.

13. Upon information and belief, Royal Philips controls Philips NA and Philips RS in the manufacturing, selling, distributing and supplying of the recalled CPAP, Bi-Level PAP and mechanical ventilator devices, including but not limited to the DreamStation CPAP Machine used by Plaintiff.

14. Upon information and belief, Defendant Philips NA is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly owned subsidiary of Royal Philips.

15. Upon information and belief, Defendant Philips RS is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS is a wholly owned subsidiary of Royal Philips. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.

16. Upon information and belief, Defendant PHUSA is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. PHUSA is a wholly owned subsidiary of Royal Philips.

17. Upon information and belief, Defendant Philips Healthcare is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Cambridge, Massachusetts 02141. That at all times hereinafter mentioned, it has been engaged in the sale, distribution and marketing of medical equipment including, but not limited to, the Philips DreamStation CPAP machine.

18. Upon information and belief, that at all times hereinafter mentioned, the Defendant, Health System Services, Ltd., was and still is a New York domestic business corporation duly organized under §402 of New York State Business Corporation Law. That at all times hereinafter mentioned, the Defendant, Health System Services, Ltd., has its principal place of business in Niagara Falls, New York. Venue is in Niagara County pursuant to CPLR 503 based upon Defendant, Health System Services, Ltd.'s principal place of business located at 6867 Williams Road, Niagara Falls, New York 14304, Niagara County.

JURISDICTION AND VENUE

19. Upon information and belief, at all relevant times, Defendant Royal Philips conducted business in the State of New York; transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; derived substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury to a person or property with the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

20. Upon information and belief, at all relevant times, Defendant Royal Philips shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times, Defendant Royal Philips was engaged in the business of designing, manufacturing, distributing, selling and marketing the subject device.

21. Upon information and belief, at all relevant times, Defendant Royal Philips NA transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; manufactured, distributed, designed and sold, the subject device with the serial number J2125235256ED.

22. Upon information and belief, at all relevant times, Defendant Philips NA is a Delaware corporation with its principal place of business located in Cambridge, Massachusetts. Defendant Philips NA is a wholly owned subsidiary of Defendant Royal Philips. Upon information and belief, Defendant Philips NA manages the operation of Defendant Royal Philips' various lines of business, including Philips RS. The sole member of Defendant Philips NA is Defendant PHUSA, which is a Delaware corporation with its principal place of business place of business in Cambridge, Massachusetts.

23. Upon information and belief, at all relevant times, Defendant Philips NA did business and contracted to supply goods or services in the State of New York; derived substantial profits from its sales in the State of New York; and committed a tortious act within the State of New York causing injury to a person or property within the State of New York.

24. Upon information and belief, at all relevant times, Defendant Philips NA was engaged in the business of designing, manufacturing, distributing, selling and marketing the subject device; shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce; transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302

25. Upon information and belief, at all relevant times, Defendant PHUSA is a Delaware corporation with its principal place of business in Cambridge, Massachusetts. Defendant PHUSA is a holding company that is the sole member of Defendant Philips NA.

26. Upon information and belief, at all relevant times, Defendant PHUSA shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times, Defendant PHUSA transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; derived substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury to a person or property with the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

27. Upon information and belief, at all relevant times, Defendant Philips RS is a Delaware corporation with its principal place of business in Pittsburgh, Pennsylvania. Defendant Philips RS was formerly operated under the business name Respironics, Inc. Defendant Royal Philips acquired Respironics, Inc. in 2008.

28. Upon information and belief, at all relevant times, Defendant Philips RS shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times, Defendant Philips RS was engaged in the business of designing, manufacturing, distributing, selling and marketing the subject device.

29. Upon information and belief, at all relevant times, Defendant Philips RS transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; did business in the State of New York; derived substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury

to a person or property within the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

30. Upon information and belief, at all relevant times, Defendant PHC is a Delaware company with its principal place of business in Cambridge, Massachusetts. At all relevant times, Defendant PHC was a foreign corporation, organized and existing pursuant to and by virtue of the laws of the State of Delaware that has authorization to do business in the State of New York.

31. Upon information and belief, at all relevant times, Defendant PHC shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times herein, Defendant PHC was engaged in the business of distributing, selling, promoting, advertising and marketing the subject device.

32. Upon information and belief, at all relevant times, Defendant PHC was and still is a corporation conducting business in the State of New York; Defendant PHC transacted business within the State of New York and/or contracted to supply goods or services in the State of New York; derived substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury to a person or property within the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

33. Upon information and belief, Defendant HSS is a New York company with its principal place of business in Niagara Falls, New York. Defendant HSS distributed, shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to New York through the stream of commerce. At all relevant times, Defendant HSS was engaged in the business of distributing, selling, promoting, advertising and marketing the subject device; was and still is a corporation conducting business in the State of New York; contracted to supply goods or services in the State of New York; derived

substantial profits from its sales in the State of New York; committed a tortious act within the State of New York causing injury to a person or property with the State of New York; and, as a result, is subject to the laws of the State of New York pursuant to CPLR 302.

34. Upon information and belief, at all relevant times, Defendants (other than HSS) were the mere alter egos or instrumentalities of each other. There is such a unity of interest and ownership between Defendants that the separate personalities of their entities ceased to exist. Defendants (other than HSS) operated as a single enterprise, equally controlled each other's business affairs, commingled their assets and funds, disregarded corporate formalities and used each other as a corporate shield to defeat justice, perpetuate fraud and evade contractual and/or tort liability.

35. Upon information and belief, at all relevant times, Defendants acted in all respects as agents or apparent agents of one another. Upon information and belief, at all relevant times, Defendants acted in concert in the designing, manufacturing, marketing, promoting, advertising and selling of devices for the treatment of obstructive sleep apnea, including the subject device. Defendants combined their property and labor in a joint undertaking for profit, with rights of mutual control over each other, rendering them jointly liable to Plaintiffs.

36. Upon information and belief, Defendants' actions in marketing, distributing and selling their devices in New York should have led them to reasonably anticipate being brought into Court in New York.

37. Upon information and belief, Defendants have sufficient "minimum contacts" with New York that subjecting them to personal jurisdiction in New York does not offend traditional notions of fair play and substantial justice.

38. As detailed below, upon information and belief, Plaintiff Sharon Lis, age 55, suffered injuries from the subject device that Defendants negligently designed and/or

manufactured, sold and distributed. Thus, Defendants committed a tort in New York that caused injuries in New York and the Court has personal jurisdiction over Defendants under New York State's Long Arm Statute.

39. Upon information and belief, this Court has personal jurisdiction over Defendants Royal Philips, Philips NA, Philips RS, PHUSA, PHC and HSS because of their systematic and continuous contacts with New York as well as their maintenance of a registered agent for service of process in New York. Federal diversity jurisdiction does not exist because Defendant HSS is a resident and corporate citizen of New York with its headquarters located in Niagara County, New York.

40. This Court is a proper venue for this civil action because Defendant HSS has its principal place of business in Niagara County at 6867 Williams Road, Niagara Falls, New York and committed the tortious acts at issue in this Complaint in Niagara County, New York and other locations in New York. This Court's exercise of personal jurisdiction over Defendants comports with due process.

FACTUAL ALLEGATIONS

The Philips DreamStation CPAP Machine

41. Obstructive sleep apnea ("OSA") is a sleeping disorder in which breathing is disrupted temporarily during sleep periods when breathing stops or becomes very shallow. OSA is associated with fatigue, daytime sleepiness, interrupted sleep, or snoring, among other symptoms.

42. CPAP therapy helps treat sleep apnea by preventing the person's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

43. Bi-PAP therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air pressure in an individual's airway.

44. At all relevant times, Defendants developed, manufactured, marketed, sold, and distributed a lineup of CPAP and BiLevel PAP devices under the Philips "Sleep & Respiratory Care" portfolio. These devices are designed to assist individuals with a number of sleep, breathing and other respiratory conditions, including OSA.

45. Philips' flagship CPAP/BiPAP machine product family is known as the "DreamStation" family line, which includes the original DreamStation, launched in October 2015 and the DreamStation Go (a travel version). Phillips sold DreamStation products through its subsidiary Respironics, that Philips acquired in 2008.

46. Philips used PE-PUR Foam in the subject device even though it was widely known that this foam is susceptible to hydrolysis.[1] Philips brought the subject device to market through the FDA's 510(k) clearance process, which is less stringent than the FDA's Pre-Market Approval ("PMA") application process. Having placed the subject device on the market, Philips assumed various duties under federal and state law, including the duty to investigate complaints and injuries and report adverse events. Philips sold the subject device as a "clinically proven" treatment for sleep disorders, exposing users of the subject device such as Sharon at the known (to Defendants) and undisclosed risk of serious and debilitation injury. The subject device failed to comply with "current good manufacturing practice" requirements ("GMPs") and other obligations imposed by FDA regulations. For example, the PE-PUR Foam in the subject device degrades and exposes patients to toxic particles and VOCs, some of which are known or suspected carcinogens.

[1] Poly*ether* polyurethan foam, which is less prone to hydrolysis, was an available safer alternative.

47. Since 2008, Philips has received hundreds of thousands of complaints of foam degradation in the subject devices. Instead of acting, Philips turned a blind eye to the problem and actively concealed it.

Philips Knew Of The Dangers Of Pe-Pur Foam Since At Least 2015

48. In 2021, an FDA investigation concluded that Philips knew as early as 2015 – *i.e.*, three years before Sharon acquired the DreamStation CPAP machine that ultimately caused her cancer – that Defendants' CPAP machines were unsafe:

> Beginning in 2015, Philips received data from a variety of sources regarding degradation of the PE-PUR foam contained within the recalled devices, including complaints, test reports, information from suppliers, and information from another entity owned by Philips' parent company. Philips failed to adequately evaluate this data and incorporate it into its CAPA [Corrective and Preventive Actions] system for further investigation and potential mitigation, as required by current good manufacturing practice requirements codified in 21 C.F.R. § 820.100.[2]

49. The FDA's determination was based in part on twenty-one (21) site inspections of Philips' Murrysville, Pennsylvania facility between August 26, 2021, and November 9, 2021. The lead FDA investigator, Katelyn A. Staub-Zamperini, memorialized the agency's finding in a 28-page FDA, 483 Report issued on November 9, 2021.[3]

50. In connection with its investigation, the FDA learned that Philips had received numerous complaints from customers about degradation of the foam in its Recalled Devices from at least as early as 2008:

> [A] query of your firm's consumer complaints from 01/01/2008 to current, for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black, **resulted in over 222,000 complaints, and over 20,000 of which occurred between 2008 to 2017 and involved Trilogy devices.** Additionally, your firm performed a foam related complaint data analysis in April 2021 on complaints confirmed to be related to or involve foam degradation issues. The raw complaint data documents that **30 Trilogy related complaints were received from 2014 to**

[2] https://www.fda.gov/media/158129/download (last accessed June 16, 2022) ("5l8(b) Notice"), at 6.
[3] A 483 Report is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. A redacted version of the 483 report is available here: https://www.fda.gov/media/l 54244/download (last accessed June I6, 2022).

2017, and 1,254 related complaints were received across all products containing the affected foam, from 2014 to 2021.[4]

51. The FDA also concluded that "[n]o formal investigation, risk analysis, or CAPA[5] were initiated, performed, or documented [by or on behalf of Philips], in response to the at least 222,000 complaints that could potentially be related to foam degradation and received from 2008 to 2017."[6] Further, the FDA determined that Philips "was made aware of polyester polyurethane foam degradation issues in/around October 2015 . . ."[7]

52. The FDA also found that Philips' analysis of consumer complaints was defective in that it "was not adequately performed to identify or detect quality problems";[8] that "potential foam degradation in Trilogy ventilator devices is not an isolated incident, and you [Philips] also have not documented a detailed rationale for why harm is not likely to occur again, as required by your Health Hazard Evaluation's instructions";[9] and that Philips' "risk analysis is inadequate or was not performed when appropriate or within an appropriate time frame of your firm becoming aware" of these issues.[10]

53. On May 2, 2022, the FDA issued a formal notice to Philips pursuant to Section 518(b) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360h(b) (the "518(b) Notice").[11]

54. The 518(b) Notice stated that "there is sufficient evidence for FDA to determine that the devices subject to the recall present an unreasonable risk of substantial harm to the public health" and "that there are reasonable grounds to believe that the recalled devices that Philips

[4] 483 Report at 12 (emphasis added).
[5] A Corrective and Preventative Action ("CAPA") refers to procedures that medical device manufactures must follow to identify and attempt to correct when a quality problem is detected. *See* 21 C.F.R. § 820.100.
[6] *Id.* at 16.
[7] 483 Report at 18.
[8] 483 Report at 16.
[9] *Id.* at 13.
[10] *Id.* at 3.
[11] https://www.fda.gov/media/158129/download (last accessed June 16, 2022).

manufactured after November 2015 were not properly manufactured with reference to the state of the art as it existed at the time of the devices' manufacture."[12]

55. The FDA also concluded that "[t]his risk is not the unavoidable byproduct of current ventilator, CPAP machine, and BiPAP machine technologies. Indeed, Philips and its competitors market ventilators, CPAP machines, and BiPAP machines that do not use PE-PUR Foam."[13]

56. The FDA's findings are directly applicable to the Philips DreamStation CPAP machine that caused Sharon's lung cancer.

57. Knowing about these safety issues with the PE-PUR Foam, Philips tested the foam material used in its Recalled Devices. According to the FDA, "this testing spoke only to the limited finding that in the case of the [redacted] foam samples 'returned from service in a Pacific rim location,' spectroscopy results were 'consistent with an environmental/chemical exposure causing base polymer cleavage and embrittlement of the material."[14] Nonetheless, based on the results of this limited testing, Philips concluded that no escalation to a CAPA process was required.

58. Philips was alerted to more warning signs of the dangers of the subject device as it continued to ask its supplier about the properties of the PE-PUR Foam it was continuing to put in medical devices that millions of its customers, including Sharon, were breathing through nightly to help their sleeping disorders with no way to know that they were exposing themselves to deadly respiratory conditions and cancers.

Philips Opened An Internal Investigation Into Foam Degradation In Mid-2018

59. On April 12, 2018, almost to the day when Sharon acquired and began to use the subject device, Philips opened a precursor to a formal CAPA, referred to by Philips as a CAPA

[12] *Id.* at 2.
[13] *Id.* at 6
[14] 518(b) Notice at 7.

INV 0988, "to investigate complaints related to potential foam degradation for the Trilogy devices in Australia and to determine what actions should be taken."[50]

60. On June 20, 2018, Philips closed CAPA INV 0988.[15] According to the FDA, Philips implemented "a preventative maintenance procedure for Trilogy devices, but Philips did not verify the effectiveness of this measure."[16]

61. The FDA pointed out that Philips' informal CAPA INV[17] related to these Trilogy devices did "not include, investigate, or examine all of your firm's CPAP and BiPAP medical devices, which also include similar air path assemblies and/or the affected polyester polyurethane foam, which is susceptible to degradation."[18] But Philips had acknowledged to the FDA that it had "received approximately eighty complaints related to foam degradation, **on non-Trilogy ventilator devices,** from 2014 to 2017."[19]

62. The FDA concluded that Philips had not "adequately established" procedures for initiating CAPA procedures.[20] Specifically, the FDA faulted Philips for not initiating a "formal" CAPA after receiving "various complaints alleging foam degradation in Trilogy ventilator devices" and then closing its informal investigation just two months later without "verify[ing] the effectiveness" of the limited "preventative maintenance procedure for Trilogy devices."[21]

63. Philips continued to receive more information that suggested that the PE-PUR Foam was prone to degradation. According to the FDA, "[a] follow-up email amongst your firm's [Philips'] personnel, dated 08/24/2018, states that testing confirmed that the affected foam breaks

---

[15] 483 Report at 15.
[16] 518(b) Notice at 8.
[17] The 483 Report explained that Philips's practice at the time was to first open CAPA requests- called "CAPA INVs"-as a precursor to a formal CAPA, but this could only occur if approved by a "CAPA Review Board" or delegate. *See* 483 Report at 14-15.
[18] *Id.* at 15.
[19] *Id.* at 16 (emphasis supplied).
[20] *Id.* at 15.
[21] 518(b) Notice at 8.

down in high heat and high humidity environments, which concurred with Trilogy ventilator related complaints . . . ."[22]

64. Nonetheless, Philips continued manufacturing and selling the Recalled Devices containing PE-PUR Foam and failed to warn users such as Sharon of the known risks of serious injury from continuing to use the subject device.

Philips Opened A Formal CAPA In 2019

65. In June 2019, Philips finally initiated a formal CAPA, numbered CAPA 7211, related to the issues associated with the PE-PUR Foam. But as the FDA explains:

> Even then, that CAPA failed to evaluate all relevant data. Philips' search of FDA's Manufacturer and User Facility Device Experience (MAUDE) database in connection with CAPA 7211 identified only three medical device reports (MDRs) associated with potential foam degradation involving Trilogy ventilators between January 2011 and January 2021. Yet an MOR analysis conducted by Philips in 2018 had already identified 17 documented complaints related to foam degradation in Trilogy ventilators, and at least 14 of those 17 complaints had related MDRs. Similarly, Philips' analysis of foam degradation-related complaints conducted in connection with CAPA 7211 identified 1,254 complaints confirmed to be related to foam degradation between 2014 and April 2021 across all affected products, yet this analysis failed to include several complaints confirmed to be related to foam degradation in Trilogy ventilators that were documented in 2018 in connection with **CAPA INV 0988.**[23]

66. Philips continued to test the PE-PUR Foam while the CAPA was underway. A Biological Risk Assessment dated July 2, 2020, found that "the biological and toxicological risks from exposure to degraded PE-PUR Foam are of concern. . . ."[24]

67. Another internal "Biological Risk Assessment" dated December 10, 2020 – and "conducted as a result of field reports/complaints regarding degraded sound abatement foam in

[22] 483 Report at 18.
[23] 518(b) Notice at 8-9.
[24] 483 Report at 7; *see also id.* ("Philips Respironics Inc. (PRI) was made aware in May 2019 that four CPAP units were returned to a service center with degraded sound abatement foam.")

various CPAP and ventilator products"[25] – described the risks that degraded polyurethane foam posed to humans in no uncertain terms:

> The cytotoxicity and positive genotoxicity results observed from degraded PE-PUR foam samples **indicate a potential patient risk. Potential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure.** Overall, based on an understanding of the toxicological significance of the foam degradants and the results of the ISO 10993 testing to include mutagenic responses in both a bacterial and mammalian system, **the degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to those patient populations who are exposed to degraded PE-PUR foam.**[26]

68. An additional Philips' Biocompatibility Risk Assessment dated January 11, 2021, concurred that degraded PE-PUR Foam "presents a significant biological risk to patients," and goes on to state that "[p]otential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure."[27]

69. Ultimately, in CAPA 7211, Philips concluded that "the cause of the foam degradation condition is long-term exposure to environmental conditions of high temperature combined with high humidity" and restated that "the cause of degradation was due to chemical breakdown of the foam due to exposure to water caused by long-term exposure to environmental conditions."[28]

70. Based on its investigation, the FDA concluded that Philips' upper management was aware of the foam degradation issues, discussed it at numerous management review meetings, and yet delayed doing anything about it – thereby knowingly placing users of its products such as Sharon at risk of serious injury or death:

> [F]irm management, including management with executive responsibility, were aware of potential foam degradation issues concerning CPAPs, BiPAPs, and Trilogy

[25] *Id.* at 8.
[26] *Id.* at 7-8 (emphasis added).
[27] *Id.* at 8.
[28] 518(b) Notice at 10.

> ventilators since at least 01/31/2020, or earlier, and implemented no further corrective actions until April 2021.
>
> Polyester polyurethane foam degradation issues concerning CPAPs, BiPAPs, and Trilogy Ventilators were discussed at all [redacted] management review meetings, since the 2019 [redacted], dated 01/31/2020 . . . . Additionally, your firm [Philips] became aware of this issue and related field complaints in at least 2015 or earlier.[29]

Until The Recall, Philips Advertised Its Breathing Machines As Safe And Effective

71. At no point prior to April 2021, when Philips first disclosed foam issues to its shareholders, did Philips even hint that there was a dangerous condition in the subject devices. Instead, Philips held itself out as a trusted brand and "global leader in the sleep and respiratory markets."[30] Philips further assures consumers like Sharon that its "sleep therapy systems are designed with the needs of care practitioners and patients in mind," and that its "quality systems reflect [Philips'] commitment to providing enhanced patient comfort," among other things. And it has long advertised its CPAP and BiPAP Machines as "clinically proven" treatment for sleep disorders.[31]

72. Philips boasts that it has the "most prescribed CPAP systems by U.S. sleep physicians."[32] The CPAP and BiPAP machines routinely cost from seven or eight hundred dollars to thousands of dollars per machine, and the ventilators cost more than several thousands of dollars per machine.

In April And May 2021, Philips Launched The DreamStation 2

73. Two months prior to the recall, Philips announced on April 13, 2021, that it was launching the DreamStation 2, a next-generation machine in its DreamStation product family. The DreamStation 2 does not contain PE-PUR Foam.

---

[29] 483 Report at 24.
[30] http://www.respironics.com/product library (last accessed June 16, 2022).
[31] https://www.usa.philips.com/healthcare/solutions/sleep (last accessed June 16, 2022).
[32] *See* https://www.usa.philips.com/healthcare/solutions/sleep/sleep-therapy (last accessed June 16, 2022) (citing 2016 Philips survey).

74. Less than two weeks after its launch of the DreamStation 2, on April 26, 2021, Philips finally announced what it had known for years – that its previous generation DreamStation products including the subject device posed serious health risks to users.[33]

75. Even then, Philips' April 26, 2021 statement to investors did not disclose the full extent of its knowledge about the risks posed by the PE-PUR Foam and attempted to deflect the blame on factors such as ozone cleaners. The FDA later rejected this notion, concluding that "the unreasonable risk associated with the products was not caused by the use of ozone cleaning agents, nor did the use of ozone to clean the products constitute a failure to exercise due care."[34]

76. When Philips finally did issue a recall on June 14, 2021, Philips advised CPAP and BiPAP users such as Sharon to "[d]iscontinue use of [their] device." Unfortunately for Sharon, the catastrophic damage to her lungs was already done.

77. On June 14, 2021, as a result of extensive ongoing review following the announcement on April 26, 2021, Philips issued a recall notification for specific affected devices, including the subject device.[35]

78. In its recall notification, Philips identified examples of potential risks which include exposure to degraded PE-PUR Foam particles and exposure to chemical emissions from the PE-PUR Foam material.

79. Philips reported that, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be

[33] https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-first-quarter-results-2021.html (last accessed June 16, 2022).
[34] 518(b) Notice at 10 (emphasis in original).
[35] On July 22, 2021, the FDA upgraded Philips' recall to its most serious classification, Class I: "A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."

life-threatening or cause permanent impairment or require medical intervention to preclude permanent impairment.

80. According to Philips' recall notice, the PE-PUR Foam used in Recalled Devices puts Recalled Device users at risk of suffering from the following health harms: "Particulate exposure can cause headache, irritation [skin, eye and respiratory tract], inflammation, respiratory issues and possible toxic and carcinogenic effects[;]" whereas the "potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting and possible toxic and carcinogenic effects."

81. At all times material, all Defendants participated in and unreasonably and unjustly profited from the manufacture, distribution and sale of the Recalled Devices and unreasonably put users of the Recalled Devices at risk of developing adverse health effects, including cancer.

The Plaintiffs

82. Sharon brings this action on behalf of herself as a purchaser and user of a recalled Philips' DreamStation Auto Continuous Positive Airway Pressure mechanical ventilator device. As a result of her usage of the subject device for three years, on or about August 11, 2022, Sharon was diagnosed with lung cancer, resulting in the need for a lobectomy.

83. Sharon's husband, Allen, brings a derivative claim for loss of consortium arising from injuries relating to those sustained by his lawful spouse, Sharon Lis.

84. At all times when Sharon used the subject device, she did so in accordance with the guidelines, manual, and instructions for use set forth by Defendants.

85. At all times when Sharon used the subject device, she did so for a purpose for which the subject device was marketed, designed, and intended by Defendants.

86. At all times when Sharon used the subject device, she did so in accordance with the directions and instructions issued by her physician who prescribed the use of the subject device.

87. After and as a result of using the subject device, Sharon has suffered personal injuries including but not limited to lung cancer. These injuries would not have occurred but for the defective nature of the subject device and Defendants' wrongful conduct alleged herein.

88. Sharon's use of the subject device caused, or significantly contributed to, her development and progression of lung cancer, which has permanently and irreparably injured her and damaged her quality of life.

89. By reason of the foregoing, Sharon has had to undergo significant treatment and will be required to undergo significant treatment in the future due to the defective nature of the subject device and/or Defendants' wrongful conduct.

90. As a result of the aforesaid conduct and subject device developed, manufactured, designed, sold, distributed, advertised, and promoted by Defendants, Plaintiff was seriously harmed and injured. As a result of such injuries, Plaintiff has suffered damages for which compensatory damages should be awarded.

91. The running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment and/or omission of critical safety information. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff and her physician, the true risks associated with the subject device created, designed, assembled, manufactured, constructed, produced, tested, packaged, labeled, marketed, advertised, promoted, made, distributed and/or sold by Defendants. Due to Defendants' actions, Plaintiff was unaware and could not have reasonably known, or learned through reasonable diligence, that she had been exposed to the risks and harms set forth and that those risks and harms were the direct and proximate result of Defendants' acts or omissions.

ARTICLE 16 ALLEGATIONS

92. If it is deemed that Article 16 of the CPLR applies to this action, the Plaintiffs assert that this action falls within one or more of the exceptions set forth in CPLR 1602 including, but not limited to, the exception for cases where a person is held liable for causing the claimant's injury by having acted with reckless disregard for the safety of others (CPLR 1602(7)); the exception for any parties found to have acted knowingly or intentionally and in concert to cause the acts or failures upon which liability is based (CPLR 1602(11)); and the exception for persons held liable in a product liability action where the manufacturer of the product is not a party to the action and jurisdiction over the manufacturer could not with due diligence be obtained (CPLR 1602(10)).

AS AND FOR A FIRST CAUSE OF ACTION IN NEGLIGENCE AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

93. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "92" of the Complaint herein with the same force and effect as if fully set forth herein.

94. Defendants had a duty to exercise reasonable care in designing, developing, researching, testing, manufacturing, marketing, supplying, promoting, selling and distributing the subject device.

95. Defendants knew, or should have known, that using the recalled devices, including the subject device, created a significantly increased risk of cancer, among other health harms.

96. Upon information and belief, the negligence of the Defendants, their agents, servants and/or employees, included but was not limited to the following acts and/or omissions: Defendants designed and developed the recalled devices, including the subject device, without thoroughly or adequately testing the devices; Defendants sold the recalled devices, including the subject device, without making proper and sufficient tests to determine the dangers to the users;

Defendants failed to adequately and correctly warn the Plaintiff, the public and the medical community of the cancer risks associated with the recalled devices, including the subject device; Defendants had a continuing duty to warn Plaintiff post-manufacture and sale of the dangers in its subject device; Defendants advertised and recommended the use of the recalled devices, including the subject device, for treatment of sleep apnea and other conditions without sufficient knowledge as to the significance of cancer risks; Defendants failed to exercise reasonable care in designing the recalled devices, including the subject device, in a manner which was dangerous to the users; Defendants negligently manufactured the recalled devices, including the subject device, in a manner which was dangerous to the users; Defendants failed to exercise reasonable care when they collectively decided to conceal information concerning cancer risks.

97. Upon information and belief, additionally, Defendants under-reported, underestimated and downplayed the serious dangers of the recalled devices, including the subject device's association with cancer and other health harms.

98. Upon information and belief, Defendants negligently compared the safety risk and/or dangers of the recalled devices, including the subject device, with other forms of treatment for sleep apnea and similar conditions.

99. Upon information and belief, Defendants also failed to warn Plaintiff and Plaintiff's physician, prior to actively encouraging the sale of the subject device, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early detection of cancer.

100. Upon information and belief, Defendants specifically failed to exercise reasonable care when they failed to accompany the subject device with proper and/or accurate warnings regarding all adverse side effects—namely cancer—associated with the use of the subject device. Once Defendants gained additional information about the Recalled Devices' association with

cancer, they failed to update their warnings and thereafter accompany the Recalled Devices with adequate warnings regarding cancer.

101. Upon information and belief, despite the fact that Defendants knew, or should have known, that the Recalled Devices caused unreasonably dangerous side effects, like cancer, they made conscious decisions to downplay these risks and continue to market, manufacture, distribute and/or sell the devices to physicians and patients, including Plaintiff Sharon Lis.

102. Upon information and belief, Defendants knew, or should have known, that consumers, such as Plaintiff Sharon Lis, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

103. Upon information and belief, Defendants' negligence was the proximate cause of Plaintiff Sharon Lis' injuries, among many other health harms, which Sharon Lis suffered and/or will continue to suffer.

104. As a result of the foregoing acts and omissions, Plaintiff Sharon Lis was caused to suffer serious and dangerous side effects that led to serious and permanent personal injuries, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications and fear of redeveloping cancer.

105. As a direct and proximate result of the Defendants' negligence, Plaintiff Sharon Lis suffered and will continue to suffer damages for which she is entitled to recovery.

106. Upon further information and belief, Defendants' conduct described herein consisted of misrepresentation, oppression, fraud and/or malice and was done with advance knowledge, conscious disregard of the safety of others and/or ratification by Defendants' officers, directors and/or managing agents.

107. Upon information and belief, despite their knowledge of the Recalled Devices' propensity to cause cancer and other serious injuries, Defendants chose profits over the safety of American citizens suffering with sleep apnea when they sought to create and market a device posing significant health risks.

108. Upon information and belief, despite having substantial information about the Recalled Devices' serious and unreasonable side effects, Defendants intentionally and recklessly failed to adequately warn the public, physicians and the medical community.

109. Upon information and belief, despite having substantial information about the Recalled Devices' serious and unreasonable side effects, Defendants failed to make the decision to pull the devices from the market after receiving indications and after receiving reports from consumers who were experiencing serious injuries associated with the use of the devices.

110. Upon information and belief, Defendants downplayed and recklessly disregarded their knowledge of the defective nature of the Recalled Devices' potential for causing serious injuries.

111. Upon information and belief, Defendants chose to do nothing to warn the public about the serious and undisclosed side effects with the Recalled Devices.

112. Upon information and belief, Defendants recklessly failed to warn and adequately instruct physicians, including Plaintiff Sharon Lis' physician, regarding the increase in reports from consumers who were experiencing serious injuries associated with the use of the Recalled Devices.

113. As a result of the negligence of the Defendants, the Plaintiff has been injured and is claiming damages in an amount exceeding the jurisdictional limits of all other courts which would otherwise have jurisdiction over this matter.

114. The intentional and willful conduct above complained of against the Defendants was aimed against the public as well as the Plaintiff; was grossly unjust and involved high moral culpability for which punitive damages should be assessed in a sum of money to be determined by the trier of fact.

AS AND FOR A SECOND CAUSE OF ACTION IN STRICT PRODUCTS LIABILITY – DESIGN DEFECT, AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

115. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "114" of the Complaint herein with the same force and effect as if fully set forth herein.

116. Upon information and belief, at all times herein mentioned, Defendants were involved in the business of researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices, including the subject device, which are defective and unreasonably dangerous.

117. Upon information and belief, the subject device was originally designed, sold and distributed by Defendants.

118. Upon information and belief, the design of the Recalled Device (including the subject device) and use of the PE-PUR Foam and the placement of the foam within the Recalled Devices, were defective and unreasonably dangerous, causing degradation and inhalation of the PE-PUR Foam and causing headaches, irritation, inflammation, respiratory issues and exposure to materials with toxic and carcinogenic effects.

119. Upon information and belief, the design of the Recalled Devices, including the subject device, and the PE-PUR Foam rendered devices, were not reasonably fit, suitable or safe for their intended purpose.

120. Upon information and belief, the Recalled Devices, including the subject device, did not perform as an ordinary consumer would expect.

121. Upon information and belief, at the time the Recalled Devices, including the subject device, were designed, manufactured, sold and distributed by Defendants, they were defective in design and unreasonably dangerous as designed.

122. Upon information and belief, at the time the subject device was sold, the defective design caused the product to unexpectedly fail to function in a manner reasonably expected by an ordinary consumer and user of such device. The defective and unreasonably dangerous design of the device was a proximate cause of the injuries and damages to the Plaintiff.

123. Upon information and belief, the dangers of the Recalled Devices, including the subject device, outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are other CPAP machines that do not use a similarly toxic foam that is subject to degradation, inhalation and ingestion.

124. Upon information and belief, safer alternative machines from other manufacturers were available that did not suffer from the defect as set forth herein and that did not have an unreasonable risk of harm as with the Recalled Devices, including the subject device, and their unsafe PE-PUR Foam.

125. Upon information and belief, the risk benefit profile of the Recalled Devices, including the subject device, was unreasonable and the Recalled Devices, including the subject device, should have had stronger and clearer warnings or should not have been sold in the market.

126. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable diligence, the defective nature of the subject device. Further, in no way could Plaintiff have known that Defendants had designed, developed, manufactured and distributed the subject device in a way as to make the risk of harm or injury outweigh any benefits.

127. The subject device was expected to and did reach Plaintiff Sharon Lis without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

128. At the time of the incident, the product was in substantially the same condition as it was at the time it was placed into the stream of commerce. No material alterations were made to the product. At the time of the incident, the product was in the same or substantially similar condition as when it left the control of Defendants.

129. The subject device was used for its intended purposes by Plaintiff Sharon Lis and the subject device was not materially altered or modified prior to its use.

130. Plaintiff Sharon Lis purchased the subject device on April 11, 2018.

131. Plaintiff Sharon Lis used the subject device regularly to treat a health condition until learning that the device was recalled on or about June 14, 2021.

132. Plaintiff Sharon Lis used the subject device in a foreseeable manner. Nonetheless, the use of the subject device was unreasonably dangerous and caused serious harm and injuries to Plaintiff.

133. The subject device was being used in a way which the Defendants intended at the time it was prescribed to Plaintiff Sharon Lis.

134. Defendants had a duty to create a device that was not unreasonably dangerous for its normal, intended use and breached this duty.

135. Upon information and belief, Defendants knew, or should have known, that the Recalled Devices, including the subject device, would be prescribed to patients and that physicians and patients were relying on them to furnish a suitable device. Further, Defendants knew, or should have known, that patients by whom the Recalled Devices would be used, such as Sharon Lis, could be and would be affected by the defective design and composition of the devices.

136. Upon information and belief, Defendants researched, designed, manufactured, tested, advertised, promoted, marketed and distributed a defective device which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiff Sharon Lis and her husband (loss of consortium), and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

137. As a direct and proximate result of Defendants' placement of the subject defective device into the stream of commerce and Plaintiff Sharon Lis' use of the product as designed, manufactured, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff Sharon Lis suffered serious physical and mental injuries including but not limited to lung cancer, debilitating injuries, harm, damages and economic loss and will continue to suffer great pain, discomfort, harm, damages and economic loss in the future as a result of being unable to attend to her ordinary affairs and she is and will remain disfigured.

138. That by reason of the foregoing, the Defendants are liable to Plaintiffs under New York's Strict Products Liability in the amount set forth in Paragraphs "113" and "114" of this Complaint.

139. That by reason of the foregoing on the part of the Defendants, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

AS AND FOR A THIRD CAUSE OF ACTION IN STRICT PRODUCTS LIABILITY – FAILURE TO WARN AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

140. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "139" of the Complaint herein with the same force and effect as if fully set forth herein.

141. Defendants had a duty to warn Plaintiff Sharon Lis regarding the defect and true risks associated with the Recalled Devices, including the subject device.

142. Upon information and belief, Defendants are liable under the theory of strict products liability. Defendants were, at all times relevant to this suit, engaged in the business of designing, manufacturing, testing, marketing, distributing and placing into the stream of commerce CPAP and BiPAP devices for sale to and for use by members of the public, including the subject device at issue in this lawsuit.

143. The subject device manufactured by Defendants reached Plaintiff Sharon Lis without substantial change and was used as directed. Upon information and belief, the subject device used by Plaintiff Sharon Lis was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Plaintiff Sharon Lis.

144. Defendants, as manufacturers of CPAP and BiPAP devices, are held to the level of knowledge of an expert in the field. Further, Defendants knew, or should have known, that warnings and other relevant information and data which they distributed regarding the defect of the device and associated health risks with the use of devices were inadequate.

145. Upon information and belief, at all times herein mentioned, Defendants designed, developed, researched, tested and knew, or should have known, about the significant cancer risks of the subject device.

146. At all times herein mentioned, Defendants advertised, promoted, marketed, sold and distributed the subject device that was used by Plaintiff Sharon Lis.

147. The subject device was expected to and did reach the usual consumers, handlers and persons coming into contact with said device without substantial change in the condition in which it was produced, manufactured, sold, distributed and marketed by the Defendants.

148. Defendants each had an independent duty and a continuing duty to warn the medical community and consumers, including Plaintiff Sharon Lis and her physician, about the significance of the risks of cancer and other health harms associated with the subject device as it became or could have become available to Defendants.

149. Plaintiff Sharon Lis used the subject device in a manner intended and foreseeable by Defendants.

150. Upon information and belief, the subject device was defective due to inadequate warnings because Defendants knew, or should have known, that the product created a significantly increased risk of cancer, among other health impacts, and failed to warn the medical community and Plaintiff's physician of the nature of such risks.

151. Defendants failed to provide adequate warnings regarding the risks of the PE-PUR Foam.

152. Upon information and belief, Defendants omitted and downplayed the significantly increased risks of cancer and other health risks associated with the Recalled Devices, including the subject device, that Defendants knew, or should have known, from previous testing and research even prior to subject device's FDA approval.

153. Upon information and belief, Defendants falsely represented to Plaintiff Sharon Lis and her physician that the subject device was safe for human use.

154. Upon information and belief, despite Defendants' obligation to unilaterally strengthen the warnings, Defendants instead chose to actively conceal this knowledge.

155. Upon information and belief, Defendants intentionally, knowingly and recklessly made these misrepresentations to induce Plaintiff's prescribing physician to prescribe and Plaintiff Sharon Lis to purchase, the Recalled subject device.

156. Plaintiff Sharon Lis and her prescribing physician did not have the same knowledge as Defendants and no adequate warning or other relevant information and data was communicated to Plaintiff Sharon Lis or her physician.

157. Among other defects, the subject device's labeling and warnings were defective because they omitted and inadequately warned of the device's risk of cancer and other health risks.

158. Upon information and belief, Defendants had information regarding the true risks but failed to warn Plaintiff Sharon Lis and her prescribing physician about the true risks stated herein and Defendants chose not to strengthen their warnings.

159. Although physicians are supposed to weigh the risks and benefits before prescribing a medical device, upon information and belief, Defendants knew that their deliberate omissions would cause physicians, including Plaintiff Sharon Lis' physician, to prescribe the subject device without being able to adequately weigh the risk of device's risk of cancer and other health risks.

160. If Defendants would have properly warned about the subject device's cancer risk and/or other health harms, Plaintiff Sharon Lis' prescribing physician would not have recommended or prescribed the subject device and Plaintiff Sharon Lis would not have purchased or used the subject device because the potential benefits of the subject device are significantly outweighed by the risk of cancer and other harms.

161. Had Defendants reasonably provided adequate warnings of cancer, such warnings would have been heeded and no healthcare professional, including Plaintiff Sharon Lis' physician, would have prescribed the subject device and no consumer, including Plaintiff Sharon Lis, would have purchased and/or used the subject device. Instead, Plaintiff's prescribing physician would have prescribed and Plaintiff Sharon Lis would have purchased and used a safer alternative device or recommended and used an alternative course of medical treatment that did not include the subject device.

162. Defendants had an obligation to provide Plaintiff Sharon Lis and Sharon Lis' physician with adequate information, data and warnings regarding the risks associated with the use of the subject device and/or that there existed safer and more or equally effective alternative devices.

163. Upon information and belief, Defendants knew that their representations to plaintiff about the Recalled Devices, including the subject device, were false in that the Recalled Devices, including the subject device, contained PE-PUR Foam that placed users like plaintiff at risk of adverse health effects from the continued inhalation of the Recalled Devices, including the subject device, which does not conform to the products' labels, packaging, advertising and statements.

164. Upon information and belief, Defendants knowingly allowed their packaging, labels, advertisements, promotional materials and websites to intentionally mislead consumers, such as Plaintiff Sharon Lis, and Plaintiff's prescribing physician.

165. Defendants marketed, promoted, distributed and sold the unreasonably dangerous and defective Recalled Devices, including the subject device, to consumers, Plaintiff Sharon Lis, and her prescribing physician without adequate warnings and other relevant information and data. Upon information and belief, through both omission and affirmative misstatements, Defendants misled Plaintiff Sharon Lis and her prescribing physician about the health risks associated with the use of the Recalled Devices, including the subject device, which resulted in injury to Plaintiff.

166. Plaintiff Sharon Lis would not have purchased, chosen, used and/or paid for all or part of the subject device and Plaintiff's prescribing physician would not have prescribed the subject device if they had known of the defect and the risks of purchasing and using the device.

167. Plaintiff Sharon Lis and Plaintiff's prescribing physician did in fact rely on these misrepresentations and omissions and Plaintiff Sharon Lis was prescribed and she purchased and used the subject device as a result of those misrepresentations and omissions. Given the deceptive

manner in which Defendants advertised, represented and otherwise promoted the Recalled Devices, including the subject device, Plaintiff's and Plaintiff's physician's reliance on Defendants' misrepresentations was justifiable.

168. By failing to provide Plaintiff Sharon Lis and her physician with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with use of the Recalled Devices, including the subject device, and/or that there existed safer and more equally effective alternative devices, Defendants breached their duty of reasonable care and safety.

169. Upon information and belief, Defendants' actions described above were performed willfully, intentionally and with reckless disregard of the life and safety of Plaintiff Sharon Lis and the public.

170. As a direct and proximate result of the subject device's defects as described herein that was placed into the stream of commerce, Plaintiff Sharon Lis developed cancer, suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has further suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost her ability to live a normal life and will continue to be so diminished in the future.

171. By reason of the foregoing, the Defendants are liable to the plaintiffs under New York Strict Products Liability in an amount set forth in Paragraphs "113" and "114" of this Complaint.

AS AND FOR A FOURTH CAUSE OF ACTION IN STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

172. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "171" of the Complaint herein with the same force and effect as if fully set forth herein.

173. Defendants are liable under the theory of strict products liability. Defendants were at all times relevant to this suit and are now engaged in the business of researching, designing, manufacturing, testing, marketing, selling, disturbing and/or placing into the stream of commerce the Recalled Devices, including the subject device, which are defective and unreasonably dangerous.

174. The subject device was expected to and did reach Plaintiff Sharon Lis without a substantial change in its condition.

175. Upon information and belief, the finished subject device deviated, in terms of construction and quality, from the specifications or planned output in a manner that made it unreasonably dangerous.

176. Upon information and belief, at all relevant times, the Recalled Devices, including the subject device, were defectively and improperly manufactured and designed by Defendants in that Defendants continued to supply consumers with the Recalled Devices despite having full knowledge that the devices posed substantial and avoidable bodily injury.

177. Upon information and belief, the foreseeable risks of the subject device were known to Defendants and could have been avoided.

178. Upon information and belief, at all relevant times, the subject device was defectively manufactured by Defendants in that its design and formulation is more dangerous than what an ordinary consumer would expect when used in an intended and reasonably foreseeable manner.

179. Upon information and belief, at all relevant times, Defendants actively deceived users that their use of the Recalled Devices posed safety risks that far outweighed any benefits.

180. Upon information and belief, the Recalled Devices, including the subject device, were defectively manufactured in that the PE-PUR Foam comprising part of the devices can

degrade into particles that enter the devices' air pathway and can off-gas certain chemicals. These characteristics cause, among other problems, cancer. Plaintiff Sharon Lis and other similarly situated consumers were unknowingly subjected to receiving different doses of toxins, carcinogens and other deleterious components and contaminants when using the Recalled Devices.

181. As a direct and proximate result of the defective manufacture of the subject device placed into the stream of commerce, Plaintiff Sharon Lis suffered and will continue to suffer damages for which she is entitled to recovery.

182. By reason of the foregoing, the Defendants are liable to the Plaintiff in an amount set forth in Paragraphs numbered "113" and "114" of this Complaint.

AS AND FOR A FIFTH CAUSE OF ACTION IN FRAUD AND MISREPRESENTATION AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

183. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "182" of the Complaint herein with the same force and effect as if fully set forth herein.

184. Upon information and belief, an inspection of Philips' internal company records conducted by the Food and Drug Administration (hereinafter "FDA") during August through November, 2021 reflects the following:

- As early as 2015, Philips was made aware that the polyester polyurethane foam in its devices was degrading during normal use;
- In 2016, Philips learned that the polyester polyurethane foam in its machines could degrade and break down in as little as one year of use;
- Records of users of Philips' devices reflect that since 2008, Philips received notice of over 222,000 complaints of degradation of the polyester polyurethane foam across all Philips' products containing the affected foam;

- By 2019, Philips was aware that biological risk assessments conducted in the field in response to reports/complaints regarding degraded and broken down polyester polyurethane foam in various CPAP products indicated the potential for cancer and other biological and toxicological risks from exposure to the degraded polyester polyurethane foam;
- As early as 2020, internal company documents revealed that the subject device failed emissions testing, exceeding tolerable limits, for the release of volatile organic compounds due to the foam's degrading.

185. As set forth above in Plaintiffs' "Factual Allegations", upon information and belief, Plaintiffs allege that Philips made affirmative misrepresentations regarding the safety and effectiveness of the subject device and omitted and withheld material safety information regarding the subject device to Plaintiff and her prescribing physician. Upon information and belief, among other wrongful conduct identified above, Philips fraudulently misrepresented the safety of its subject devices and failed to inform users and/or the medical profession that these devices containing polyester based polyurethane were breaking down into toxic particles that could be inhaled by users of these breathing machines.

186. Upon information and belief, plaintiff further alleges that during this period of time, while knowing that its polyester foam insulation devices were breaking down and releasing toxic particles that could be breathed in by the user, Philips failed to warn and continued to fraudulently misrepresent the safety of its products to users and the medical profession all to the detriment of plaintiff and others similarly situated.

187. Defendants had a duty to exercise reasonable care to those to whom they provided device information about the Recalled Devices and to all those relying on the information

provided, including Plaintiff Sharon Lis, her healthcare providers and the public in general that the devices had been tested and found to be safe and effective for treating sleep apnea.

188. Upon information and belief, Defendants, in the course of selling the Recalled Devices, supplied information about the devices through television commercials, advertisements, marketing campaigns, sales representatives, labeling and warnings.

189. Defendants breached their duty by misrepresenting the subject device's safety to the medical and healthcare community, to Plaintiff Sharon Lis and Plaintiff's prescribing physician.

190. Defendants failed to exercise reasonable care because their goal should have been to put safety before their profits by providing individuals with the realistic risks and expectations that the Recalled Devices could cause cancer and other serious injuries.

191. Defendants' representations were made without properly conducting sufficient testing and by providing insufficient warnings about the Recalled Devices' potential risks.

192. Defendants' false representations that the Recalled Devices were safe for consumers and their failure to disclose material past and existing facts of the Recalled Devices' risk of cancer were made or omitted with the intent to induce Plaintiff Sharon Lis and her prescribing physician to rely upon those facts or omissions.

193. Plaintiff Sharon Lis and her physician were unaware and did not know that the subject device was unsafe for the purpose of treating sleep apnea because it caused a significant increased risk of cancer until after she had been exposed to carcinogenic particles and gasses.

194. Plaintiff Sharon Lis and her physician justifiably relied upon the false representations and omissions of Defendants.

195. Had Defendants provided adequate warnings of cancer and other serious injuries, such warnings would have been heeded by plaintiff and her prescribing physician.

196. Had Defendants reasonably provided adequate warnings of cancer, such warnings would have been heeded and no healthcare professional, including Plaintiff Sharon Lis' physician, would have prescribed the subject device and no consumer, including Plaintiff Sharon Lis, would have purchased and/or used the subject device. Instead, Plaintiff's prescribing physician would have prescribed and Plaintiff Sharon Lis would have purchased and used a safer alternative device or recommended and used an alternative course of medical treatment that did not include the subject device.

197. As a direct and proximate result of the foregoing acts and omissions, Plaintiff Sharon Lis was caused to suffer serious and dangerous side effects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications and fear of redeveloping cancer and is entitled to an amount of damages as set forth in Paragraphs "113" and "114" of this Complaint. Plaintiffs do not allege a claim or cause of action for fraud on the FDA.

AS AND FOR A SIXTH CAUSE OF ACTION IN BREACH OF EXPRESS WARRANTY AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

198. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "197" of the Complaint herein with the same force and effect as if fully set forth herein.

199. At all relevant times, Defendants, through their advertising and promotional materials, expressly and impliedly warranted and affirmed that the subject devices' purpose was to offer a reasonably safe treatment for sleep apnea and similar health problems.

200. Upon information and belief, Defendants touted the subject devices as safe, despite knowingly having never adequately researched or tested the devices to assess their safety before placing the devices on the market and promoting them to consumers.

201. Defendants intended to make Plaintiff Sharon Lis and the general public believe the subject devices were safe.

202. Upon information and belief, Defendants knowingly mislead Plaintiff Sharon Lis and the general public to believe the subject devices were safe for use, despite knowing that the devices could lead to serious injuries, all of which Defendants knew, or by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff Sharon Lis would be victim to.

203. Upon information and belief, at all relevant times, Defendants had knowledge of the hazards and health risks posed by the Recalled Devices when used.

204. Upon information and belief, at all relevant times, Defendants willfully failed to disclose the defects and health risks of the Recalled Devices to Plaintiff Sharon Lis and the consuming public.

205. Plaintiff Sharon Lis relied, to her detriment, on the information publicized by Defendants.

206. In reliance upon these warranties as to the safety of the subject device by Defendants, Plaintiff Sharon Lis acquired/purchased and used the subject device, believing that the subject device was inherently safe.

207. Plaintiff Sharon Lis notified Defendants of the breach.

208. As a direct and proximate result of the foregoing acts and omissions, Plaintiff Sharon Lis suffered and will continue to suffer damages in an amount as set forth in Paragraphs "113" and "114" for which she is entitled to recovery.

AS AND FOR A SEVENTH CAUSE OF ACTION UNDER IMPLIED WARRANTY OF MERCHANTABILITY AGAINST THE NAMED DEFENDANTS, PLAINTIFF, SHARON LIS, ALLEGES:

209. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "208" of the Complaint herein with the same force and effect as if fully set forth herein.

210. Upon information and belief, at all relevant times, Defendants have been merchants in regard to the recalled devices, including the subject device, they created and sold to consumers.

211. Upon information and belief, Defendants breached their implied warranty of merchantability since the subject devices were defective when created and designed and do not conform with the promises represented on their labels.

212. Upon information and belief, Defendants failed to comply with merchantability requirements, as the subject devices do not achieve the ordinary purposes they advertise: a healthy treatment for respiratory conditions such as sleep apnea.

213. Beyond Defendants' own direct sales of the subject devices, Plaintiff Sharon Lis and other consumers are third-party beneficiaries of Defendants' agreements with their distributors, dealers and sellers for the distribution, dealing and sale of the Recalled Devices to consumers. Plaintiff Sharon Lis and consumers are the intended beneficiaries of Defendants' implied warranties since the Recalled Devices are manufactured with the express and intended purpose of selling the devices to consumers.

214. As a direct and proximate result of Defendants' breach of their implied warranties of merchantability regarding the subject device, Plaintiff Sharon Lis was damaged because, had she been aware of the unmerchantable condition of the subject device, she would have not acquired/purchased/used the subject device and not suffered injuries and damages from its use.

215. As a direct and proximate result of the foregoing acts and omissions, Plaintiff Sharon Lis suffered and will continue to suffer damages in an amount as set forth in Paragraphs "113" and "114" for which she is entitled to recovery.

AS AND FOR AN EIGHTH CAUSE OF ACTION UNDER LOSS OF CONSORTIUM AGAINST THE NAMED DEFENDANTS, PLAINTIFF ALLEN LIS ALLEGES:

216. Plaintiff repeats and realleges each and every allegation contained in paragraphs "1" through "215" of the Complaint herein with the same force and effect as if fully set forth herein.

217. At all relevant times, Plaintiff Allen Lis was and still is the lawful spouse of Plaintiff Sharon Lis and as such was entitled to her services.

218. At all relevant times, Plaintiff Allen Lis has been deprived of the services, society, companionship, consortium and support of his wife, Plaintiff Sharon Lis, all to his damage.

219. That by reason of the foregoing, Plaintiff Sharon Lis was compelled to seek and obtain medical aid and attention and Plaintiff Allen Lis did necessarily pay and become liable therefor, for medicines and medical care and upon information and belief, Plaintiff Sharon Lis will necessarily incur further similar expenses.

220. That by reason of the foregoing, Plaintiff Allen Lis has been damaged in an amount that exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

WHEREFORE, Plaintiffs demand judgment against the Defendants in the First, Second, Third, Fourth, Fifth, Sixth, Seventh and Eighth Causes of Action in an amount exceeding the jurisdictional limits of all other courts which would otherwise have jurisdiction over this matter; punitive damages in a sum of money to be determined by the trier of fact; and for such other and further relief as may be just and proper, together with the costs and disbursements of this action.

DEMAND FOR JURY TRIAL

221. Plaintiffs demand a jury trial on all counts in this Verified Complaint.

Dated this 10th day of August, 2023.

Michael A. Ponterio, Esq.
Lipsitz, Ponterio & Comerford LLC
424 Main Street, Suite 1500
Buffalo, NY 14202
Phone: (716) 849-0701
Fax: (716) 849-0708

Connor G. Sheehan, Esq.*
Texas Bar No. 24046827
csheehan@dunnsheehan.com
DUNN SHEEHAN LLP
5910 N. Central Expressway, Suite 1310
Dallas, Texas 75206
Phone: (214) 866-0077
Fax: (214) 866-0070
**pro hac vice application forthcoming*

Attorneys for Plaintiffs

VERIFICATION

STATE OF NEW YORK)
COUNTY OF ERIE) SS.:
CITY OF BUFFALO)

The undersigned, an attorney admitted to practice in the courts of the State of New York, shows: that deponent is a member of the firm of LIPSITZ, PONTERIO & COMERFORD LLC, the attorneys of record for the plaintiffs in the within action; that deponent has read the foregoing Verified Complaint and knows the contents thereof; that the same is true to deponent's own knowledge, except as to those matters therein stated to be alleged upon information and belief and as to those matters deponent believes it to be true. Deponent further says that the reason this verification is made by deponent and not by plaintiffs, SHARON LIS and ALLEN LIS, is because said plaintiffs are not in Erie County which is the county where deponent has his principal office.

The grounds of deponent's belief as to all matters not stated upon deponent's knowledge are as follows: records, reports and correspondence in deponent's file.

The undersigned affirms that the foregoing statements are true, under the penalties of perjury.

Dated: August 10, 2023

Michael A. Ponterio

MICHAEL A. PONTERIO, ESQ.

EXHIBIT E

Corporate Records & Business Registrations

Source Information

Information Current Through:	06/20/2021
Database Last Updated:	07/13/2021
Update Frequency:	WEEKLY
Current Date:	07/17/2021
Source:	AS REPORTED BY THE SECRETARY OF STATE OR OTHER OFFICIAL SOURCE

Company Information

Name:	PHILIPS RS NORTH AMERICA LLC
Address:	6501 LIVING PLACE PITTSBURGH, PA 15206
D&B DUNS:	08-072-8314

Filing Information

Identification Number:	1115779
Filing Date:	04/05/2017
State of Incorporation:	DELAWARE
Status:	GOOD STANDING
Business Type:	FOREIGN LIMITED LIABILITY CO
Address Type:	BUSINESS
Where Filed:	SECRETARY OF STATE/CORPORATION DIVISION 202 N CONGRESS ST STE 601 JACKSON, MS 39201

Registered Agent Information

Name:	CORPORATION SERVICE COMPANY

Name Information

Former Name:	RESPIRONICS, INC.

Principal Information

Name:	JOHN A FRANK
Title:	MANAGER
Address:	1740 GOLDEN MILE HWY MONROEVILLE, PA 15146
Name:	JACK LIBERT
Title:	MANAGER
Address:	1010 MURRY RIDGE LANE MURRYSVILLE, PA 15668
Name:	OSCAR MACEDO
Title:	MANAGER
Address:	6501 LIVING PLACE PITTSBURGH, PA 15206
Name:	SONAL MATAI
Title:	MANAGER
Address:	6501 LIVING PLACE PITTSBURGH, PA 15206
Name:	PHILIPS RS NORTH AMERICA HOLDING CORPORATION
Title:	MEMBER
Address:	222 JACOBS STREET CAMBRIDGE, MA 02141

Amendment Information

Amendments:	04/08/2021 MISCELLANEOUS ANNUAL REPORT FOR PHILIPS RS NORTH AMERICA LLC 11/10/2020 MISCELLANEOUS BUSINESS CONVERSION FOR RESPIRONICS, INC. 04/08/2020 MISCELLANEOUS ANNUAL REPORT FOR RESPIRONICS, INC. 04/11/2019 MISCELLANEOUS ANNUAL REPORT FOR RESPIRONICS, INC.

04/12/2018 MISCELLANEOUS ANNUAL REPORT FOR RESPIRONICS, INC.
04/05/2017 MISCELLANEOUS FORMATION FOR RESPIRONICS, INC.

The preceding public record data is for information purposes only and is not the official record. Certified copies can only be obtained from the official source.
The public record items reported above may have been paid, terminated, vacated or released prior to today's date.

Order Documents

Call Westlaw CourtExpress at 1-877-DOC-RETR (1-877-362-7387) for on-site manual retrieval of documents related to this or other matters. Additional charges apply.

End of Document

EXHIBIT F

CURRENCY

Information Current Through:	7/17/2021
Update Frequency:	As Current As Secretary of State
Source:	Delaware Secretary of State

COMPANY INFORMATION

Name:	PHILIPS RS NORTH AMERICA HOLDING CORPORATION

AGENT INFORMATION

Agent Name:	CORPORATION SERVICE COMPANY
Agent ID Number:	9000014
Address:	251 LITTLE FALLS DRIVE WILMINGTON, DE 19808

FILING INFORMATION

Residency:	Domestic
Entity Kind:	Corporation
Entity Type:	General
State of Incorporation:	Delaware Company
Date of Incorporation:	10-31-2020
Status:	Good Standing, 10-31-2020
Expiration Date:	Not Available
State ID Number:	4018768

STOCK INFORMATION

Total Authorized Shares:	1,000
Total Value:	$1,000.00
Stock Effective Date:	10-31-2020

TAX INFORMATION

Last Annual Report Filed:	2021
Annual Tax Assessment:	$175.00
Current Tax Estimate as of 7/17/2021	$225.00
Tax Area & Code:	A/R Filing Required

Filing History (Last 5 Filings)

Description	Pages	Filing Date	Filing Time	Effective Date
Stock Corporation	1	10-30-2020	11:51	10-31-2020

Order Documents

Call Westlaw CourtExpress at 1-877-DOC-RETR (1-877-362-7387) for on-site manual retrieval of documents related to this or other matters. Additional charges apply.

Thomson Reuters Legal is not a consumer reporting agency and none of its services or the data contained therein constitute a 'consumer report' as such term is defined in the Federal Fair Credit Reporting Act (FCRA), 15 U.S.C. sec. 1681 et seq. The data provided to you may not be used as a factor in consumer debt collection decisioning, establishing a consumer's eligibility for credit, insurance, employment, government benefits, or housing, or for any other purpose authorized under the FCRA. By accessing one of our services, you agree not to use the service or data for any purpose authorized under the FCRA or in relation to taking an adverse action relating to a consumer application.

End of Document

EXHIBIT G

Corporate Records & Business Registrations

Source Information

Information Current Through: 09/30/2021
Database Last Updated: 11/15/2021
Update Frequency: MONTHLY
Current Date: 11/23/2021
Source: AS REPORTED BY THE SECRETARY OF STATE OR OTHER OFFICIAL SOURCE

Company Information

Name: PHILIPS NORTH AMERICA LLC
Address: 222 JACOBS STREET
CAMBRIDGE, MA 02141-2289

Filing Information

Identification Number: 0408258
Filing Date: 11/22/1995
State of Incorporation: DELAWARE
Status: ACTIVE
Business Type: FOREIGN LIMITED LIABILITY CO
Address Type: MAILING
Where Filed: SECRETARY OF STATE/ CORPORATE DIVISION
STATE CAPITOL STE 152
FRANKFORT, KY 40601

Registered Agent Information

Name: CORPORATION SERVICE COMPANY
Address: 421 WEST MAIN STREET
FRANKFORT, KY 40601

Principal Information

Name: PHILIPS HOLDING USA INC
Title: MEMBER
Name: BRENT SHAFER
Title: DIRECTOR
Name: JAMES M MATTERN II
Title: DIRECTOR
Name: JOSEPH E INNAMORATI
Title: DIRECTOR
Name: BRENT SHAFER
Title: PRESIDENT
Name: JOSEPH E INNAMORATI
Title: SECRETARY
Name: JAMES M MATTERN II
Title: TREASURER

Amendment Information

Amendments: 03/14/1996 MISCELLANEOUS ASSUMED NAME CORP: EDAX INTERNATIONAL

Additional Detail Information

Additional Details: BUSINESS STANDING: GOOD

The preceding public record data is for information purposes only and is not the official record. Certified copies can only be obtained from the official source.
The public record items reported above may have been paid, terminated, vacated or released prior to today's date.

Order Documents

Call Westlaw CourtExpress at 1-877-DOC-RETR (1-877-362-7387) for on-site manual retrieval of documents related to this or other matters. Additional charges apply.

Thomson Reuters Legal is not a consumer reporting agency and none of its services or the data contained therein constitute a 'consumer report' as such term is defined in the Federal Fair Credit Reporting Act (FCRA), 15 U.S.C. sec. 1681 et seq. The data provided to you may not be used as a factor in consumer debt collection decisioning, establishing a consumer's eligibility for credit, insurance, employment, government benefits, or housing, or for any other purpose authorized under the FCRA. By accessing one of our services, you agree not to use the service or data for any purpose authorized under the FCRA or in relation to taking an adverse action relating to a consumer application.

End of Document

EXHIBIT H

Corporate Records & Business Registrations

Source Information

Information Current Through:	09/30/2021
Database Last Updated:	11/15/2021
Update Frequency:	MONTHLY
Current Date:	11/23/2021
Source:	AS REPORTED BY THE SECRETARY OF STATE OR OTHER OFFICIAL SOURCE

Company Information

Name:	PHILIPS HOLDING USA INC.
Address:	222 JACOBS STREET CAMBRIDGE, MA 02141-2289

Filing Information

Identification Number:	0989315
Filing Date:	06/26/2017
State of Incorporation:	DELAWARE
Status:	ACTIVE
Corporation Type:	PROFIT
Business Type:	CORPORATION
Address Type:	MAILING
Where Filed:	SECRETARY OF STATE/ CORPORATE DIVISION STATE CAPITOL STE 152 FRANKFORT, KY 40601

Registered Agent Information

Name:	CORPORATION SERVICE COMPANY
Address:	421 WEST MAIN STREET FRANKFORT, KY 40601

Principal Information

Name:	JOSEPH E. INNAMORATI
Title:	DIRECTOR
Name:	LING LIU
Title:	DIRECTOR
Name:	VITOR ROCHA
Title:	DIRECTOR
Name:	VITOR ROCHA
Title:	PRESIDENT
Name:	JOSEPH E. INNAMORATI
Title:	SECRETARY
Name:	LING LIU
Title:	TREASURER
Name:	PAUL CAVANAUGH
Title:	VICE PRESIDENT

Additional Detail Information

Additional Details:	BUSINESS STANDING: GOOD

The preceding public record data is for information purposes only and is not the official record. Certified copies can only be obtained from the official source.
The public record items reported above may have been paid, terminated, vacated or released prior to today's date.

Order Documents

Call Westlaw CourtExpress at 1-877-DOC-RETR (1-877-362-7387) for on-site manual retrieval of documents related to this or other matters. Additional charges apply.

Thomson Reuters Legal is not a consumer reporting agency and none of its services or the data contained therein constitute a 'consumer report' as such term is defined in the Federal Fair Credit Reporting Act (FCRA), 15 U.S.C. sec. 1681 et seq. The data provided to you may not be used as a factor in consumer debt collection decisioning, establishing a consumer's eligibility for credit, insurance, employment, government benefits, or housing, or for any other purpose authorized under the FCRA. By accessing one of our services, you agree not to use the service or data for any purpose authorized under the FCRA or in relation to taking an adverse action relating to a consumer application.

End of Document

EXHIBIT I

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LIABILITY LITIGATION MDL No. 3014

TRANSFER ORDER

Before the Panel:* Plaintiff in the Eastern District of Pennsylvania *Starner* action moves under 28 U.S.C. § 1407 to centralize this litigation in the Eastern District of Pennsylvania or, alternatively, in the Western District of Pennsylvania.[1] This litigation consists of ten actions pending in five districts, as listed on Schedule A. The parties have informed the Panel of 104 related actions pending in 31 districts.[2]

Plaintiffs in more than fifty actions responded to the motion. All support centralization, but differ as to the proposed transferee district. The suggested transferee districts include: the Northern District of California, the Middle District of Georgia, the Northern District of Georgia, the District of Kansas, the Eastern District of Louisiana, the District of Massachusetts, the Western District of Missouri, the District of Oregon, the Eastern District of Pennsylvania, the Western District of Pennsylvania, the Eastern District of Virginia, and the Southern District of West Virginia. Defendants Philips North America LLC and Philips RS North America LLC (collectively, Philips) likewise support centralization. Defendants suggest either the District of Massachusetts or the Western District of Pennsylvania as the transferee district.

On the basis of the papers filed and the hearing session held,[3] we find that the actions listed

* One or more Panel members who could be members of the putative classes in this litigation have renounced their participation in these classes and have participated in this decision.

[1] Movant also does not oppose centralization in the Eastern District of Louisiana or the District of Massachusetts.

[2] These and any other related actions are potential tag-along actions. *See* Panel Rules 1.1(h), 7.1, and 7.2.

[3] In light of the concerns about the spread of the COVID-19 virus (coronavirus), the Panel heard oral argument by videoconference at its hearing session of September 30, 2021. *See* Suppl. Notice of Hearing Session, MDL No. 3014 (J.P.M.L. Sept. 13, 2021), ECF No. 134.

on Schedule A involve common questions of fact, and that centralization in the Western District of Pennsylvania will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation. These actions share factual questions arising from Philips' recall of certain Continuous Positive Airway Pressure (CPAP), Bi-Level Positive Airway Pressure (Bi-Level PAP), and mechanical ventilator devices on June 14, 2021.[4] The recalled devices allegedly contain polyester-based polyurethane (PE-PUR) sound abatement foam that may degrade into particles or off-gas volatile organic compounds that may then be ingested or inhaled by the user, causing injury. Plaintiffs allege that defendants concealed the problems with the PE-PUR foam before the recall was announced and made misrepresentations regarding the recalled devices in connection with their marketing and sales.

Most of the actions are putative consumer class actions asserting overlapping claims for violations of state consumer protection statutes, breach of warranties, and unjust enrichment. The asserted nationwide and state classes overlap significantly. Approximately thirty actions assert individual personal injury claims. The parties support inclusion of these personal injury actions in the MDL. We concur. All of the Philips actions will raise similar factual questions regarding the recalled devices and the conduct of the recall, and will require common discovery regarding the development and safety of the recalled devices and the potential harm that can be caused by the alleged defect. *See In re Valsartan N-Nitrosodimethylamine (NDMA) Contamination Prods. Liab. Litig.*, 363 F. Supp. 3d 1378, 1381–82 (J.P.M.L. 2019) (centralizing consumer claims for economic damages with personal injury claims). Centralization will eliminate duplicative discovery; prevent inconsistent pretrial rulings, particularly with respect to class certification motions; and conserve the resources of the parties, their counsel, and the judiciary.

The Western District of Pennsylvania is an appropriate transferee district for this litigation. It appears from the parties' submissions and arguments that the recalled products were primarily manufactured by Philips RS North America LLC (formerly Philips Respironics) in Murrysville, Pennsylvania. Thus, many of witnesses and much of the documentary evidence relevant to this litigation likely will be located within the Western District of Pennsylvania. The district also presents a convenient and accessible venue for this litigation. We assign this MDL to the Honorable Joy Flowers Conti, an experienced transferee judge, who we are confident will steer this litigation on a prudent and expeditious course.

---

[4] The recalled devices include: E30 (Emergency Use Authorization); DreamStation ASV; DreamStation ST, AVAPS; SystemOne ASV4; C Series ASV; C Series S/T and AVAPS; OmniLab Advanced Plus: SystemOne (Q Series); DreamStation; DreamStation Go; Dorma 400; Dorma 500; REMStar SE Auto; Trilogy 100 Ventilator; Trilogy 200 Ventilator; Garbin Plus, Aeris, LifeVent Ventilator; A-Series BiPAP Hybrid A30; Philips A-Series BiPAP V30 Auto Ventilator; Philips A-Series BiPAP A40; and Philips A-Series BiPAP A30.

IT IS THEREFORE ORDERED that the actions listed on Schedule A and pending outside the Western District of Pennsylvania are transferred to the Western District of Pennsylvania and, with the consent of that court, assigned to the Honorable Joy Flowers Conti for coordinated or consolidated pretrial proceedings.

PANEL ON MULTIDISTRICT LITIGATION

Karen K. Caldwell
Chair

Catherine D. Perry
Matthew F. Kennelly
Roger T. Benitez
Nathaniel M. Gorton
David C. Norton
Dale A. Kimball

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LIABILITY LITIGATION MDL No. 3014

SCHEDULE A

District of Delaware

SHRACK v. KONINKLIJKE PHILIPS N.V., ET AL., C.A. No. 1:21−00989

Middle District of Florida

EMMINO v. PHILIPS NORTH AMERICA LLC, ET AL., C.A. No. 8:21−01609

Middle District of Georgia

HELLER v. KONINKELIJKE PHILIPS N.V. ET AL., C.A. No. 4:21−00111

District of Massachusetts

MANNA v. KONINKLIJKE PHILIPS N.V., ET AL., C.A. No. 1:21−11017
SHELTON v. KONINKLIJKE PHILIPS N.V., ET AL., C.A. No. 1:21−11076
GRIFFIN v. KONINKLIJKE PHILIPS N.V., ET AL., C.A. No. 1:21−11077
OLDIGS v. PHILIPS NORTH AMERICA LLC, ET AL., C.A. No. 1:21−11078
SCHUCKIT v. PHILIPS NORTH AMERICA LLC, ET AL., C.A. No. 1:21−11088
BOUDREAU, ET AL. v. PHILIPS NORTH AMERICA LLC, ET AL., C.A. No. 1:21−11095

Eastern District of Pennsylvania

STARNER v. KONINKLIJKE PHILIPS N.V., ET AL., C.A. No. 2:21−02925

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

SHARON LIS and ALLEN LIS,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	
	§	
KONINKLIJKE PHILIPS N.V.;	§	
PHILIPS NORTH AMERICA LLC;	§	CASE NO. _________
PHILIPS RS NORTH AMERICA LLC;	§	
PHILIPS HOLDING USA, INC.;	§	
PHILIPS HEALTHCARE; and	§	
HEALTH SYSTEM SERVICES, LTD.,	§	
	§	
Defendants.	§	

DECLARATION OF WILLIAM B. MONAHAN
IN SUPPORT OF NOTICE OF REMOVAL

I, William B. Monahan, hereby declare as follows:

1. I am over 18 years of age, of sound mind, and otherwise competent to make this Declaration. The evidence set out in this Declaration is based on my personal knowledge unless otherwise stated.

2. I am a partner of the law firm Sullivan & Cromwell LLP resident in its New York office, 125 Broad Street, New York, NY 10004-2498.

3. To my knowledge, there is no legal entity called "Philips Healthcare," and it is not clear which entity (if any) Plaintiffs appear to be referencing. However, to the extent this entity is a juridical entity, Sullivan & Cromwell LLP represents it in this action, along with Koninklijke Philips N.V., Philips North America LLC, and Philips Holding USA Inc. All consent to the removal of this case from the Supreme Court of the State of New York, County of Niagara, in

which this case is now pending at Case Number E180656/2023, to the United States District Court for the Western District of New York.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 30th day of August, 2023.

Respectfully submitted,

/s/William B. Monahan
William B. Monahan
SULLIVAN & CROMWELL LLP
125 Broad Street
New York, NY 10004-2498
Telephone: +1.212.558.7375
Facsimile: +1.212.558.3588
monahanw@sullcrom.com

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS
Sharon Lis and Allen Lis

DEFENDANTS
See attached.

(b) County of Residence of First Listed Plaintiff ______
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant ______
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)
See attached.

Attorneys (If Known)
See attached.

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☒ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

- ☐ 1 Original Proceeding
- ☒ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from another district (specify)
- ☐ 6 Multidistrict Litigation
- ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (**Do not cite jurisdictional statutes unless diversity**):
28 USC 1332 Diversity of Citizenship

Brief description of cause:

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE ______ DOCKET NUMBER ______

DATE
08/31/2023

SIGNATURE OF ATTORNEY OF RECORD
Gary Adler

FOR OFFICE USE ONLY

RECEIPT # ______ AMOUNT ______ APPLYING IFP ______ JUDGE ______ MAG. JUDGE ______

Print | Save As... | Export as FDF | Retrieve FDF File | Reset

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity**. Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

Attachment to Civil Cover Sheet

Defendants

Koninklijke Philips N.V.
Philips North America LLC
Philips RS North America LLC
Philips Holding USA, Inc.
Philips Healthcare
Health System Services, Ltd.

Plaintiffs' Attorneys

Michael A. Ponterio, Esq.
Lipsitz, Ponterio & Comerford LLC
424 Main Street, Suite 1500
Buffalo, NY 14202
Telephone: +1.716.849.0701
Fax: +1.716.849.0708

Connor G. Sheehan, Esq.
Texas Bar No. 24046827
Dunn Sheehan LLP
5910 N. Central Expressway, Suite 1310
Dallas, Texas 75206
Telephone: +1.214.866.0077
Fax: +1.214.866.0070
csheehan@dunnsheehan.com

Defendants' Attorneys

Gary Adler
MORGAN, LEWIS & BOCKIUS LLP
101 Park Ave.
New York, NY 10178-0060
Telephone: +1.212.309.6140
Facsimile: +1.212.309.6001
gary.adler@morganlewis.com

Attorneys for Defendant Philips RS North America LLC

William B. Monahan
SULLIVAN & CROMWELL LLP
125 Broad Street
New York, NY 10004-2498
Telephone: +1.212.558.7375
Facsimile: +1.212.558.3588
monahanw@sullcrom.com

Attorneys for Defendants Philips North America LLC and Philips Holding USA, Inc.